





# **FORM 10-K/A**

**CELGENE CORP /DE/ – CELG**

**Filed: March 21, 2005 (period: December 31, 2004)**

Amendment to a previously filed 10-K

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
Amendment No. 2  
To  
FORM 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (Fee Required)

For the fiscal year ended December 31, 2004

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (No Fee Required)

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-16132

CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	22-2711928
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification)

86 Morris Avenue Summit, New Jersey	07901
(Address of principal executive offices)	(Zip Code)

(908) 673-9000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None  
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.01 per share

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is an accelerated filer (as defined in 12b-2 of the Act).

Yes ☒ No ☐

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2004, the last business day of the registrant's most recently completed second quarter, was \$4,694,329,287 based on the last reported sale price of the registrant's Common Stock on the NASDAQ National Market on that date. There were 165,269,970 shares of Common Stock outstanding as of March 1, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2004. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

Part III, Item 10, Directors and Executive Officers of the Registrant;  
Part III, Item 11, Executive Compensation;  
Part III, Item 12, Security Ownership of Certain Beneficial Owners and Management and related Stockholder Matters;  
Part III, Item 13, Certain Relationships and Related Transactions;  
Part III, Item 14, Principal Accountant Fees and Services.

This Annual Report on Form 10-K/A for the fiscal year ended December 31, 2004 supersedes, in its entirety, a draft document captioned "Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the fiscal year ended December 31, 2004" that was filed on March 16, 2005, as a result of technical inadvertence by a financial printer.

CELGENE CORPORATION  
ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. BUSINESS

We are a multi-national integrated biopharmaceutical company, incorporated in 1986 as a Delaware corporation. We are primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory-related diseases through the regulation of cells, genes and proteins associated with diseases. We had total revenue of \$377.5 million in 2004 and net income of \$52.8 million. We had an accumulated deficit of \$234.4 million at December 31, 2004.

We continue to build a global discovery, development and commercialization platform for drug and cell-based therapies that allows us to both create and retain significant value within our therapeutic franchise areas of cancer and immune-inflammatory diseases. This target-to-therapeutic platform integrates both small molecule and cell-based therapies and spans the key functions required to generate a broad, deep and diverse pipeline of new drugs and cell therapy candidates, including: (i) cell biology, genomics, proteomics and informatics technologies for identifying and validating clinically important therapeutic targets; (ii) high throughput screening systems combined with diverse and focused compound libraries for discovering new drug leads; (iii) medicinal chemistry and structure-based drug design for optimizing drug candidates; (iv) IN VITRO and IN VIVO models of disease for preclinical evaluation of drug efficacy and safety; and (v) a clinical and regulatory organization highly experienced in the successful development of pharmaceutical agents. The ongoing development of immunomodulatory drugs (ImiDs), cell-signaling inhibitors, as well as cellular and tissue therapeutics may allow us to provide physicians and clinicians worldwide with a more comprehensive and integrated set of therapeutic solutions for managing complex human diseases such as cancer and immune-inflammatory-related diseases.

On August 31, 2000, we acquired Signal Pharmaceuticals, Inc., now Celgene Research & Development, a privately held San Diego-based biopharmaceutical company focused on the discovery and development of drugs that regulate genes and proteins associated with diseases. Celgene Research & Development now operates as a wholly owned subsidiary of Celgene Corporation.

On December 31, 2002, we acquired Anthrogenesis Corp., or Celgene Cellular Therapeutics, a privately held New Jersey-based biotherapeutics company and cord blood banking business, which is developing the technology for the recovery of stem cells from human placental tissues following the completion of full-term, successful pregnancies. Celgene Cellular Therapeutics, or CCT, now operates as a wholly owned subsidiary of Celgene Corporation.

On October 21, 2004, we acquired all of the outstanding shares of Penn T, the UK-based manufacturer of THALOMID(R), the current flagship product of our commercial franchise. This acquisition expanded our corporate capabilities and enabled the Company to control manufacturing for THALOMID(R) worldwide. Through manufacturing contracts acquired in this purchase, Celgene increased its participation in the potential growth of THALOMID(R) revenues in key international markets.

COMMERCIAL STAGE PROGRAMS: Our commercial programs include pharmaceutical sales of THALOMID(R) and ALKERAN(R), a licensing agreement with Novartis for FOCALIN(R) and the entire RITALIN(R) family of drugs and biotherapeutic products and services, including; LIFE BANK(TM), BIOVANCE(TM) and AMBIO DRY(TM) through CCT

THALOMID(R) (THALIDOMIDE): THALOMID(R), which had net product sales totaling \$308.6 million in 2004, was approved by the U.S. Food and Drug Administration, or FDA, in July 1998 for the treatment of acute cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, and as maintenance therapy to prevent and suppress cutaneous manifestation recurrences. ENL, an inflammatory complication of leprosy, is a chronic bacterial disease associated with excess Tumor Necrosis Factor alpha, or TNF(alpha) production. Although leprosy is relatively rare in the United States, the disease afflicts millions worldwide. ENL occurs in about 30% of leprosy patients and is characterized by skin lesions, acute inflammation, fever and anorexia.

We distribute THALOMID(R) in the United States through our 197-person U.S. pharmaceutical commercial organization. Working with the FDA, we developed a proprietary strategic comprehensive education and distribution program with methods for the safe and appropriate use of THALOMID(R), the "System for Thalidomide Education and Prescribing Safety", or S.T.E.P.S. (R).

In October 2004, Celgene received an approvable letter from the FDA in response to our THALOMID(R) Supplemental New Drug Application, or sNDA, which we filed in December 2003, for the treatment of multiple myeloma. Multiple myeloma is the second most common blood cancer, affecting approximately 50,000 people in the United States. About 14,000 new cases of multiple myeloma are diagnosed each year and there are an estimated 11,000 deaths. We expect to complete the resubmission of the application in the second quarter of 2005 with final action from the FDA expected later in the year.

Additionally, THALOMID(R) is under development as a potential treatment for other cancers. There are more than 100 clinical studies worldwide examining the potential of this compound as a single agent or in combination therapy. As a result of these clinical studies and subsequent publications, and inclusion in the National Comprehensive Cancer Network, or NCCN, guidelines, physicians are prescribing THALOMID(R) for use in a number of cancers.

THALOMID(R) is the first drug approved under a special "Restricted Distribution for Safety" regulation. Our innovative S.T.E.P.S. system includes managed delivery programs for products or drugs that are either teratogens (causing birth defects) or have other adverse effects that make them contraindicated for certain patients. This patented program includes comprehensive physician, pharmacist and patient education. All patients are required to use contraception, and female patients of child-bearing potential are given pregnancy tests regularly. All patients are subject to other requirements, including informed consent. Physicians are also required to comply with the educational, contraception counseling, informed consent, pregnancy testing and other elements of the program. Under the S.T.E.P.S. program, automatic refills are not permitted and each prescription may not exceed four weeks' dosing. A new prescription is required each month.

Our S.T.E.P.S. intellectual property estate includes five U.S. patents expiring between the years 2018 and 2020 which cover methods of delivering drugs, including THALOMID(R), in a manner that significantly decreases the risks of adverse events. Two of these patents were issued in 2003 and expand the scope of coverage contained in the previously issued patents. S.T.E.P.S. is designed as a blueprint for pharmaceutical products that offer life-saving or other important therapeutic benefits but have potentially problematic side effects. Furthermore, we hold patents protecting methods of use for THALOMID(R) to treat symptoms associated with abnormal concentrations of TNF $\alpha$  and unrestricted blood vessel growth that expire after 2012.

In November 2004 Celgene granted a non-exclusive license to the four companies who manufacture and distribute (sell) isotretinoin (Accutane(R)) for the rights to Celgene's patent portfolio directed to methods for safely delivering the product to potentially high-risk patient populations.



ALKERAN(R): In March 2003, we entered into a supply and distribution agreement with GlaxoSmithKline to distribute, promote and sell ALKERAN(R) (melphalan), a therapy approved by the FDA for the palliative treatment of multiple myeloma and for palliation of carcinoma of the ovary. Under the terms of the agreement, we purchase ALKERAN(R) tablets and ALKERAN(R) for injection from GlaxoSmithKline and distribute the products in the United States under the Celgene label. The agreement has an initial term of three years and is automatically extended by successive one-year periods, unless at least one year prior to the renewal date either party advises the other party that it elects not to extend the agreement. This agreement is strategically valuable to us because it provides us with an approved oncology product that complements our drug candidates, THALOMID(R) and REVLIMID(R), which are demonstrating potential in late-stage clinical trials for the treatment of multiple myeloma and myelodysplastic syndromes. At the 2004 American Society of Hematology, or ASH, meeting, clinical trial data was presented. In combination with other anti-cancer therapeutics, including THALOMID(R), ALKERAN(R) was a key component of several investigational multiple myeloma studies which reported positive results.

RITALIN(R) FAMILY OF DRUGS: We have a major collaboration with Novartis Pharma AG concerning the entire RITALIN(R) family of drugs. We developed FOCALIN(R) (d-MPH), the chirally pure version of RITALIN(R), which is approved for the treatment of attention deficit disorder and attention deficit hyperactivity disorder, or ADHD, in school-age children. The use of chirally pure compounds, such as FOCALIN(R), can result in significant clinical benefits. Many non-chirally pure pharmaceuticals contain two configurations, known as isomers, which are mirror images of each other. Generally these isomers interact differently with their biological targets, causing one isomer to have a beneficial effect for one target and the other isomer to have a beneficial effect on another target, or in some cases, one isomer may have either no effect or potentially an undesirable side effect with respect to a target. In April 2000, we granted Novartis an exclusive license (excluding Canada) for the development and marketing of FOCALIN(R) and long acting drug formulations in return for substantial milestone payments and royalties on FOCALIN(R) and the entire RITALIN(R) family of drugs. In 2002, Novartis launched FOCALIN(R) and RITALIN(R) LA, the long-acting version of RITALIN(R), in the United States, following regulatory approval.

Three separate studies presented at the 51st annual meeting of the American Academy of Child and Adolescent Psychiatry indicated that FOCALIN(R) XR, the long-acting version of FOCALIN(R), may help adults and children manage ADHD symptoms. Pediatric studies showed that FOCALIN(R) XR (dexamethylphenidate HCl) extended release capsules may help treat ADHD symptoms for 12 hours. ADHD is one of the most common psychiatric disorders of childhood and is estimated to affect five to seven percent of children and approximately four percent of the adult population in the U.S.

The Division of Neuropharmacological Drug Products at the FDA has accepted for review a New Drug Application, or NDA, submitted by Novartis, seeking approval to market FOCALIN(R) XR for the treatment of pediatric and adult ADHD. FDA action on the FOCALIN(R) XR NDA is expected in the first half of 2005.

We have retained the exclusive commercial rights to FOCALIN(R) and FOCALIN(R) XR for oncology-related disorders, such as chronic fatigue associated with chemotherapy. We have completed a double-blinded randomized placebo-controlled trial evaluating the use of FOCALIN(R) for the treatment of fatigue symptoms associated with chemotherapy. We are evaluating potential clinical and regulatory development strategies for this indication.

CELLULAR THERAPEUTICS: With the acquisition of Anthrogenesis Corporation in December 2002, we acquired a biotherapeutics company developing stem cell therapies and biomaterials derived from human placental tissue. CCT has organized its business into three main units: (1) private stem cell banking for transplantation, (2) stem cell therapies and (3) biomaterials for organ and tissue repair. CCT has developed proprietary methods for producing placental biomaterials for organ and tissue repair which includes the BIOVANCE(TM) and AMBIODRY(TM) products. Additionally, CCT has developed proprietary

technology for collecting, processing and storing placental stem cells with potentially broad therapeutic applications in cancer, autoimmune, cardiovascular, neurological and other diseases.

**PRECLINICAL AND CLINICAL-STAGE PIPELINE:** Our preclinical and clinical-stage pipeline of new drug candidates, in addition to our cell therapies, is highlighted by multiple classes of small molecule, orally administered therapeutic agents designed to selectively regulate disease-associated genes and proteins. The drug candidates in our pipeline are at various stages of preclinical and clinical development. Successful results in preclinical or Phase I/II clinical studies may not be an accurate predictor of the ultimate safety or effectiveness of the drug candidate

**IMMUNOMODULATORY DRUGS (IMiDs(R)):** IMiDs are novel small molecule, orally available compounds that modulate the immune system through multiple mechanisms of action. We have advanced four IMiDs into development: REVLIMID(R) (CC-5013), ACTIMID(TM) (CC-4047) and CC-11006 are being evaluated in human clinical trials and CC-10015 is presently undergoing preclinical evaluation.

Our IMiD class of drug candidates is covered by an extensive and comprehensive intellectual property estate of U.S. and foreign issued patents and pending patent applications including composition-of-matter and use patents and patent applications.

**REVLIMID(R) (LENALIDOMIDE):** is a small molecule, orally-available immunomodulatory drug being investigated in clinical trials as a potential treatment for myelodysplastic syndromes (MDS) and multiple myeloma, malignant blood disorders that affect approximately 300,000 and 200,000 people worldwide, respectively. It is currently being studied in a number of clinical trials, the most advanced of which are Phase III trials - in the United States (MM-009) and in Europe (MM-010) - for previously treated multiple myeloma patients. On March 7, 2005, we announced that based on a review of the data by the Independent Data Monitoring Committee, the trials were being unblinded due to the meeting of pre-specified stopping rules for meeting efficacy targets.

Approximately 30 clinical trials are currently evaluating REVLIMID(R) in the treatment of a broad range of conditions, including multiple myeloma, the blood cell disorders known as myelodysplastic syndromes, or MDS, and solid tumor cancers. Preliminary clinical data from several of these trials have been announced with additional data to be presented at major medical meetings in 2005

REVLIMID(R) has been granted fast track designation in both multiple myeloma and MDS by the FDA. It has also received orphan drug status both in the United States and Europe which provides potential regulatory and financial benefits to products receiving regulatory approval with this designation. On the basis of the Phase II study (MDS-003), we plan to file a New Drug Application with the FDA for the 5q deletion MDS indication in the first quarter of 2005

In addition to our pivotal Phase III and accelerated Phase II REVLIMID(R) trials, the Southwest Oncology Group, the Eastern Cooperative Oncology Group, and the Cancer and Leukemia Group B, three of the largest adult cancer clinical trial organizations in the world, selected REVLIMID(R) for large clinical studies in randomized controlled Phase III trials designed to evaluate the safety and efficacy of REVLIMID(R) in multiple myeloma patients.

At the 2004 American Society of Hematology meeting, new data evaluating REVLIMID(R) as a potential therapeutic approach for the treatment of patients with multiple myeloma and MDS was presented. Encouraging preliminary reports were presented in various stages of multiple myeloma and MDS. Additional data is expected to be presented at medical meetings throughout 2005.

ACTIMID(TM) is one of the most potent Immunomodulatory drugs that we are developing. Currently, ACTIMID is in Phase II trials to determine its potential safety and efficacy as a treatment for multiple myeloma and prostate cancer. ACTIMID and REVLIMID(R) have different activity profiles which may lead to their evaluation in different diseases or stages of disease.

CC-11006: is a molecule we have identified as a potential treatment for chronic inflammatory diseases, many of which are not well served today. CC-11006 entered Phase I human clinical trials in 2004. Following the completion of Phase I trials, we will review our development options.

PDE4/TNF(ALPHA) INHIBITORS: Our Phosphodiesterase 4, or PDE4/TNF(alpha), inhibitors provide a potentially novel small molecule approach to treating chronic inflammatory diseases. Our lead PDE-4 compound is CC-10004. During 2004, CC-10004 entered Phase II clinical trials in exercise-induced asthma and psoriasis after successfully completing Phase I testing in healthy human volunteers. This compound is well tolerated with good bioavailability and pharmacokinetics in humans. Data from these Phase II trials is expected in late 2005.

BENZOPYRANS: CC-8490, our lead compound in this category, is in Phase I clinical trials for glioblastoma, a form of brain cancer, with investigators at the National Cancer Institute. In Phase I trials in healthy human volunteers, CC-8490 has been shown to be well-tolerated. Animal studies have demonstrated that the compound could have an important effect on solid tumors such as non-small cell lung cancer and colon cancer.

KINASE INHIBITORS: We have multiple target and drug discovery projects underway this year in the field of kinase inhibition. Our kinase inhibitor platform includes inhibitors of the c-Jun N-terminal kinase pathway, or JNK. This pathway has been associated with the regulation of a number of important disease indications. CC-401, our lead JNK inhibitor, successfully completed a Phase I trial in healthy volunteers. We plan to initiate a Phase II Acute Myelogenous Leukemia, or AML, trial later this year.

TUBULIN INHIBITORS: Celgene scientists have discovered a new chemical class of anti-cancer compounds called tubulin inhibitors that stop cancer cells from proliferating by impeding cell division. In preclinical models, our proprietary tubulin inhibitors have demonstrated activity against drug-resistant cancer cells, inhibition of inflammatory cytokines and anti-angiogenic activity.

LIGASE INHIBITORS: We are conducting extensive discovery research in the field of ligases, intracellular mechanisms that control the degradation of selected proteins within cells. Celgene is identifying drug targets and compounds that regulate ligase pathways with the goal of controlling cellular proliferation and survival. Such compounds would have the potential to be an important new class of anti-cancer and anti-inflammatory therapeutics.

STEM CELLS: Stem cell based therapies offer the potential to provide disease-modifying outcomes for serious diseases which today lack adequate therapy. We are researching the potential of cells and tissues derived from the placenta and umbilical cord blood in a number of potential indications. In December 2004, Celgene filed an investigational new drug application (IND) with the FDA for our initial stem cell trial in sickle cell anemia. Celgene researchers are also exploring the potential of our small molecule compounds to lead to selective differentiation and expansion of pluripotent stem cells.

# CELGENE PRODUCT OVERVIEW

Our products and our primary product candidates are targeted to address a variety of key medical needs. These products and product candidates and our development and/or marketing partners, if any, are described in the following table

PRODUCT/ PRODUCT CANDIDATES	DISEASE INDICATION	COLLABORATOR	STATUS
THALOMID(R)	ENL Multiple Myeloma MDS Prostate Cancer Inflammatory Diseases		Marketed Phase III trials ongoing Phase III trial ended. Phase II trials ongoing. Phase II trials ongoing.
ALKERAN(R)	Multiple Myeloma &Ovarian Cancer	GlaxoSmithKline	Marketed.
RITALIN(R) FAMILY OF DRUGS: FOCALIN(R)	ADHD Cancer Fatigue	Novartis	Marketed. Phase II trial completed.
FOCALIN(R) XR	ADHD	Novartis	NDA filed
RITALIN(R) LA	ADHD	Novartis	Marketed
IMiDS: REVLIMID(R)	Multiple Myeloma  Multiple Myeloma  Myelodysplastic Syndromes  Myelodysplastic Syndromes with 5Q deletion  Solid Tumor Cancers and Additional Hematological Malignancies	  Various Cooperative Oncology Groups	  Phase II and Pivotal Phase III SPA trials ongoing. Major Phase III trials ongoing and initiating. Accelerated Phase II trials ongoing. Phase III studies initiating. Accelerated Phase II trials ongoing Phase III studies initiating. Phase I/II trials ongoing and expanded. Additional trials planned.

PRODUCT/ PRODUCT CANDIDATES	DISEASE INDICATION	COLLABORATOR	STATUS
ACTIMID CC-11006 CC-10015	Multiple Myeloma Prostate Cancer Inflammatory Inflammatory Diseases		Phase I/II trial completed Phase II trial ongoing. Phase I studies ongoing. Preclinical studies ongoing.
PDE4 AND TNF (ALPHA) INHIBITORS: CC-10004 CC-11050	Asthma Psoriasis Inflammatory Diseases		Phase II trial ongoing. Phase II trial ongoing. Preclinical studies ongoing.
BENZOPYRANS: CC-8490 CC-227113	Cancer Cancer	National Cancer Institute ("NCI")	Phase I/II trial ongoing Preclinical studies ongoing.
KINASE INHIBITORS: CC-401 JNK CC0389359	Cancer/Inflammatory Diseases Ischemia/Reperfusion Injury		Phase I trials completed Additional trials planned. Preclinical studies ongoing
TUBULIN INHIBITORS: CC-5079	Cancer		Preclinical studies ongoing
LIGASES INHIBITORS:	Cancer		Preclinical studies ongoing.
STEM CELLS AND TISSUE PRODUCTS:			
LIFEBANK(TM) USA BIOVANCE(TM) AMBIODRY(TM) Cord Blood Cells	Private Stem Cell Banking Wound Covering Ophthalmology Sickle Cell Anemia	Okto Ophtho Inc.	Marketed. Marketed. Marketed. Phase I IND filed

Clinical trials are typically conducted in three sequential phases, although the phases may overlap.

#### PHASE I CLINICAL TRIALS

Phase I human clinical trials usually involve a small number of healthy volunteers or patients. The tests study a drug's safety profile, and may include the safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

## PHASE II CLINICAL TRIALS

In Phase II clinical trials, controlled studies are conducted on a limited number of patients with the targeted disease. An initial evaluation of the drug's effectiveness on patients is performed and additional information on the drug's safety is obtained.

## PHASE III CLINICAL TRIALS

This phase typically includes multi-center trials and involves a larger patient population. During the Phase III clinical trials, physicians monitor patients to determine efficacy and to gather further information on safety.

Successful results in preclinical studies or Phase I or II studies may not be an accurate predictor of the ultimate safety or effectiveness of the drug.

## PATENTS AND PROPRIETARY TECHNOLOGY

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our inventions, and also to rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We own or have exclusively licensed more than 128 U.S. patents and have over 157 additional U.S. patent applications pending. Our U.S. patents include patents for a method of delivering a teratogenic drug to a patient while preventing fetal exposure as well as patents for delivering drugs to patients while restricting access to the drug to those for whom the drug is contra-indicated. We also have patent applications pending which are directed to these inventions, and are seeking worldwide protection. While we have a policy to seek worldwide patent protection for our inventions, we have foreign patent rights corresponding to most but not all of our U.S. patents. Although THALOMID(R) is approved for use associated with ENL, we do not have patent protection relating to the use of THALOMID(R) to treat ENL.

Our research at Celgene Research and Development in San Diego has led us to seek patent protection for molecular targets and drug discovery technologies, as well as therapeutic and diagnostic products and processes. More specifically, proprietary technology has been developed for use in molecular target discovery, the identification of regulatory pathways in cells, assay design and the discovery and development of pharmaceutical product candidates. As of December 2004, and included in those inventions described above, our San Diego subsidiary owned, in whole or in part, over 32 issued U.S. patents and had approximately 47 U.S. patent applications pending. An increasing percentage of our San Diego subsidiary's recent patent applications have been related to potential product candidates or compounds. They also hold licenses to U.S. patents and pending U.S. patent applications, some of which are licensed exclusively or sub-licensed to third parties in connection with sponsored or collaborative research relationships.

CCT, our cellular therapeutics subsidiary, seeks patent protection for the collection, processing and uses of mammalian placental tissue and placental stem cells, and biomaterials recovered from the placenta. As of December 2004, CCT owned, in whole or in part, more than 16 pending U.S. patent applications, and holds licenses to certain U.S. patents and pending applications, including those related to cord blood collection and storage.

In August 2001, we entered into an agreement, termed the New Thalidomide Agreement, with EntreMed, Inc., Children's Medical Center Corporation and Bioventure Investments, KFT relating to patents and patent applications owned by CMCC, which agreement superceded several agreements already in place between CMCC, EntreMed and us. Pursuant to the New Thalidomide Agreement, CMCC directly granted to us an exclusive worldwide, royalty-bearing license under the relevant patents and patent applications relating to thalidomide. Several U.S. patents have already issued to CMCC in this patent family and certain of these patents expire in 2014. Corresponding foreign patent applications and additional U.S. patent applications are still pending.

In addition to the New Thalidomide Agreement, we entered into an agreement with CMCC and EntreMed in December 2002, pursuant to which we have been granted an exclusive worldwide, royalty-bearing license to certain CMCC patents and patent applications relating to thalidomide analogs, or the New Analog Agreement. The New Analog Agreement was executed in connection with the settlement of certain pending litigation between and among us, EntreMed and the U.S. Patent and Trademark Office relating to the allowance of certain CMCC patent applications covering thalidomide analogs. These patent applications had been licensed exclusively to EntreMed in the field of thalidomide analogs. In conjunction with the settlement of these suits, we acquired equity securities in EntreMed, and EntreMed

terminated its license agreements with CMCC relating to thalidomide analogs. In turn, under the New Analog Agreement, CMCC exclusively licensed to Celgene these patents and patent applications, which relate to analogs, metabolites, precursors and hydrolysis products of thalidomide, and stereoisomers thereof.

The New Analog Agreement grants us control over the prosecution and maintenance of the licensed thalidomide analog patent rights. The New Analog Agreement also grants us an option to inventions in the field of thalidomide analogs that may be developed at CMCC in the laboratory of Dr. Robert D'Amato, pursuant to the terms and conditions of a separate Sponsored Research Agreement negotiated between CMCC and us.

Under an agreement with The Rockefeller University, pursuant to which we have made a lump sum payment and issued stock options to The Rockefeller University and the inventors, we have obtained certain exclusive rights and licenses to manufacture, have manufactured, use, offer for sale and sell products that are based on compounds which were identified in research carried out by The Rockefeller University and us that have activity associated with TNF(alpha). In particular, The Rockefeller University identified a method of using thalidomide and certain thalidomide-like compounds to treat certain symptoms associated with abnormal concentrations of TNF(alpha), including those manifested in septic shock, cachexia and HIV infection. In 1995, The Rockefeller University was issued a U.S. patent which claims such methods. This U.S. patent expires in 2012 and is included in the patent rights exclusively licensed to us under the agreement with The Rockefeller University. The Rockefeller University did not seek corresponding patents in any other country.

Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties where necessary and conduct our business without infringing the proprietary rights of others. The patent positions of pharmaceutical and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. In addition, the coverage sought in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of our owned or licensed pending patent applications will result in the issuance of patents or, if any patents are issued, whether they will be dominated by third-party patent rights, whether they will provide significant proprietary protection or commercial advantage or whether they will be circumvented or infringed upon by others.

There can be no assurance that additional patents will issue to us from any of our pending applications or that, if patents issue, such patents will provide us with significant proprietary protection or commercial advantage. Moreover, there can be no assurance that any of our existing patents will not be dominated by third-party patent rights or provide us with proprietary protection or commercial advantage. Nor can we guarantee that these patents will not be either infringed, invalidated or circumvented by others. Finally, we cannot guarantee that our patents or pending applications will not be involved in, or be defeated as a result of any interference proceedings before the U.S. Patent and Trademark Office.

With respect to patents and patent applications we have licensed-in, there can be no assurance that additional patents will issue to any of the third parties from whom we have licensed patent rights, either with respect to thalidomide or thalidomide analogs, or that, if any new patents issue, such patents will not be dominated by third-party patent rights or provide us with significant proprietary protection or commercial advantage. Moreover, there can be no assurance that any of the existing licensed patents will provide us with proprietary protection or commercial advantage. Nor can we guarantee that these licensed patents will not be either infringed, invalidated or circumvented by others, or that the relevant agreements will not be terminated. Any termination of the licenses granted to Celgene by CMCC could have a material adverse effect on our business, financial condition and results of operations.



Since patent applications filed in the United States on or before November 28, 2000 are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we, or our licensors, were the first to make the inventions covered by each of the issued patents or pending patent applications or that we, or our licensors, were the first to file patent applications for such inventions. In the event a third party has also filed a patent for any of our inventions, we, or our licensors, may have to participate in interference proceedings before the U.S. Patent and Trademark Office to determine priority of invention, which could result in the loss of a U.S. patent or loss of any opportunity to secure U.S. patent protection for the invention. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us.

We are aware of U.S. patents that have been issued to third parties claiming subject matter relating to the NF-k(Beta) pathway, which could overlap with technology claimed in some of our owned or licensed NF-k(Beta) patents or patent applications. We believe that one or more interference proceedings may be initiated by the U.S. Patent and Trademark Office to determine priority of invention for this subject matter. While we cannot predict the outcome of any such proceedings, in the event we do not prevail, we believe that we can use alternative methods for our NF-k(Beta) drug discovery program for which we have issued U.S. patents that are not claimed by the subject matter of the third party patents. We are also aware of third-party U.S. patents that relate to the use of certain PDE 4 inhibitors to treat inflammation.

We may in the future have to prove that we are not infringing patents or we may be required to obtain licenses to such patents. However, we do not know whether such licenses will be available on commercially reasonable terms, or at all. Prosecution of patent applications and litigation to establish the validity and scope of patents, to assert patent infringement claims against others and to defend against patent infringement claims by others can be expensive and time-consuming. There can be no assurance that, in the event that claims of any of our owned or licensed patents are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity relating to the subject matter delineated by such patent claims and may have a material adverse effect on our business. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the products or processes covered by the disputed rights, subject to significant liabilities to such third party and/or be required to license technologies from such third party. Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention or that any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Competitors may choose to file oppositions to patent applications, which have been deemed allowable by foreign patent examiners. Furthermore, even if our owned or licensed patents are determined to be valid and enforceable, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. Additionally, for these same reasons, we cannot be sure that patents of a broader scope than ours may be issued and thereby create freedom to operate issues. If this occurs we may need to reevaluate pursuing such technology, which is dominated by others' patent rights, or alternatively, seek a license to practice our own invention, whether or not patented.

We also rely upon unpatented, proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies

for any such breach or that our trade secrets, proprietary know-how and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology or that such technology will not be found to be non-proprietary or not a trade secret.

#### GOVERNMENTAL REGULATION

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. Most, if not all, of our therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal and in some cases state statutes and regulations also govern or impact upon the manufacturing, testing for safety and effectiveness, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals, and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products or the manufacturing or quality control procedures used in their production may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure by us, our suppliers of manufactured drug product, collaborators or licensees to obtain or maintain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of our products and our ability to receive product revenue, license revenue or profit sharing payments.

The activities required before a pharmaceutical may be marketed in the United States begin with preclinical testing not involving human subjects. Preclinical tests include laboratory evaluation of a product candidate's chemistry and its biological activities and the conduct of animal studies to assess the potential safety and efficacy of a product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an IND, which must be reviewed by the FDA primarily for safety considerations before proposed clinical trials in humans can begin.

Typically, clinical trials involve a three-phase process. In Phase I, clinical trials are generally conducted with a small number of individuals, usually healthy human volunteers, to determine the early safety and tolerability profile and the pattern of drug distribution and metabolism within the body. If the Phase I trials are satisfactory, Phase II clinical trials are conducted with groups of patients in order to determine preliminary efficacy, dosing regimes and expanded evidence of safety. In Phase III, large-scale, multi-center, adequately powered and typically placebo-controlled comparative clinical trials are conducted with patients in an effort to provide enough data for the statistical proof of efficacy and safety required by the FDA and others for marketing approval. In some limited circumstances, Phase III clinical trials may be modified to allow the evaluation of safety and efficacy based upon (i) comparisons with approved drugs, (ii) comparison with the historical progression of the disease in untreated patients, or (iii) the use of surrogate markers, together with a commitment for post-approval studies. In some cases, as a condition for New Drug Application, or NDA, approval, further studies (Phase IV) are required to provide additional information concerning the drug. The FDA requires monitoring of all aspects of clinical trials, and reports of all adverse events must be made to the agency, both before and after drug approval. Additionally, we may have limited control over studies conducted with our proprietary compounds if such studies are performed by others, (e.g., cooperative groups and the like).

The results of the preclinical testing and clinical trials are submitted to the FDA as part of an NDA for evaluation to determine if the product is sufficiently safe and effective for approval to commence commercial sales. In responding to an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. When an NDA is approved, the developer and marketer of the drug must employ a system for obtaining reports of experience and side effects that are associated with the drug and make appropriate submissions to the FDA.

Pursuant to the Orphan Drug Act, a sponsor may request that the FDA designate a drug intended to treat a "rare disease or condition" as an "orphan drug." A rare disease or condition is defined as one which affects less than 200,000 people in the United States, or which affects more than 200,000 people, but for which the cost of developing and making available the drug is not expected to be recovered from sales of the drug in the United States. Upon the approval of the first NDA for a drug designated as an orphan drug for a specified indication, the sponsor of that NDA is entitled to exclusive marketing rights in the United States for such drug for that indication for seven years unless the sponsor cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease. This period of exclusivity is concurrent with any patent exclusivity that relates to the drug. Orphan drugs may also be eligible for federal income tax credits for costs associated with the drug's development. Possible amendment of the Orphan Drug Act by the U.S. Congress and possible reinterpretation by the FDA has been discussed by regulators and legislators. FDA regulations reflecting certain definitions, limitations and procedures for orphan drugs initially went into effect in January 1993 and were amended in certain respects in 1998. Therefore, there is no assurance as to the precise scope of protection that may be afforded by orphan drug status in the future or that the current level of exclusivity and tax credits will remain in effect. Moreover, even if we have an orphan drug designation for a particular use of a drug, there can be no assurance that another company also holding orphan drug designation will not receive approval prior to us for the same indication. If that were to happen, our applications for that indication could not be approved until the competing company's seven-year period of exclusivity expired. Even if we are the first to obtain approval for the orphan drug indication, there are certain circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity. First, particularly in the case of large molecule drugs, a question can be raised whether the competing product is really the "same drug" as that which was approved. In addition, even in cases in which two products appear to be the same drug, the agency may approve the second product based on a showing of clinical superiority compared to the first product.

Among the conditions for NDA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures continually conform with the FDA's current Good Manufacturing Practice, or cGMP (cGMP are regulations established by the FDA that govern the manufacture, processing, packing, storage and testing of drugs intended for human use). In complying with cGMP, manufacturers must devote extensive time, money and effort in the area of production and quality control and quality assurance to maintain full technical compliance. Manufacturing facilities and company records are subject to periodic inspections by the FDA to ensure compliance. If a manufacturing facility is not in substantial compliance with these requirements, regulatory enforcement action may be taken by the FDA, which may include seeking an injunction against shipment of products from the facility and recall of products previously shipped from the facility.

Failure to comply with applicable FDA regulatory requirements can result in informal administrative enforcement actions such as warning letters, recalls or adverse publicity issued by the FDA or in legal actions such as seizures, injunctions, fines based on the equitable remedy of disgorgement, restitution and criminal prosecution.

Steps similar to those in the United States must be undertaken in virtually every other country comprising the market for our products before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis or at all. In addition, regulatory approval of drug pricing is required in most countries other than the United States. There can be no assurance that the resulting pricing of our drugs would be sufficient to generate an acceptable return to us.

#### COMPETITION

The pharmaceutical and biotechnology industries in which we compete are each highly competitive. Our competitors include major pharmaceutical and biotechnology companies, many of which have considerably greater financial, scientific, technical and marketing resources than us. We also experience competition in the development of our products and processes from universities and other research institutions and, in some instances, compete with others in acquiring technology from such sources.

Competition in the pharmaceutical industry, and specifically in the oncology and immune-inflammatory areas being addressed by us, is particularly intense. Numerous pharmaceutical and biotechnology companies have extensive anti-cancer and anti-inflammatory drug discovery, development and commercial resources. Bristol-Myers Squibb Co., Amgen Inc., Genentech, Inc., Sanofi-Aventis SA., Novartis AG, AstraZeneca PLC., Eli Lilly and Company, F. Hoffmann-LaRoche Ltd, Pharmion Corp., Millennium Pharmaceuticals, Inc., SuperGen, Inc., Cell Therapeutics, Inc., Vertex Pharmaceuticals Inc., Biogen Idec Inc., Merck and Co., Inc. and Pfizer Inc. are among some of the companies researching and developing new compounds in the oncology and immunology fields.

The pharmaceutical and biotechnology industries have undergone, and are expected to continue to undergo, rapid and significant technological change. Also, consolidation and competition are expected to intensify as technical advances in each field are achieved and become more widely known. In order to compete effectively, we will be required to continually upgrade and expand our scientific expertise and technology, identify and retain capable personnel and pursue scientifically feasible and commercially viable opportunities.

Our competition will be determined in part by the indications and geographic markets for which our products are developed and ultimately approved by regulatory authorities. An important factor in competition will be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can develop products, complete clinical trials and approval processes and supply commercial quantities of products to the market are expected to be important competitive factors. Competition among products approved for sale will be based, among other things, on product efficacy, safety, convenience, reliability, availability, price, third-party reimbursement and patent and non-patent exclusivity

#### SIGNIFICANT ALLIANCES

From time to time we enter into collaborative research and/or license agreements with other pharmaceutical and biotechnology companies by which, in exchange for the rights to certain compounds, the partnering company will provide funding in the form of upfront payments, milestone payments or direct research funding, and may also purchase product and pay royalties on product sales. The following are our most significant collaborations.

NOVARTIS PHARMA AG: We entered into an agreement with Novartis in April 2000 in which we granted to Novartis an exclusive license (excluding Canada) for the development and marketing of FOCALIN(R) (d-

MPH). We received a \$10.0 million upfront payment in July 2000, a \$5.0 million milestone payment upon the acceptance of the NDA filing by the FDA in December 2000, a \$12.5 million milestone payment upon approval by the FDA to market FOCALIN(R) in November 2001 and a \$7.5 million milestone payment in 2004 for filing an NDA for FOCALIN(R) XR. We are currently selling FOCALIN(R) to Novartis as well as receiving royalties on all of Novartis' RITALIN(R) family of ADHD-related products. The research portion of the agreement ended in June 2003. We may receive an additional milestone payment in 2005 for U.S. regulatory approval of FOCALIN(R) XR.

PHARMION: In November 2001, we entered into an agreement with Pharmion Corporation and Pharmion GmbH ("Pharmion") pursuant to which we granted an exclusive license to Pharmion for the use of our intellectual property covering thalidomide. In addition, we entered into a second agreement with Pharmion, pursuant to which we granted to Pharmion an exclusive license to use S.T.E.P.S.(R) in all countries other than North America, Japan, China, Taiwan and Korea in exchange for licensing payments and, upon regulatory approvals, royalties based on commercial sales. The thalidomide license agreement terminates upon the tenth anniversary following regulatory approval in the United Kingdom. Pursuant to the S.T.E.P.S.(R) license agreement, we are entitled to receive \$0.3 million on a quarterly basis beginning in January 2002, until initial regulatory approval in the United Kingdom is received. In April 2003, we entered into a collaborative clinical trials development agreement whereby Pharmion agreed to provide to us an aggregate of \$8.0 million in funding for further clinical development of THALOMID(R) through December 2005. We received three installments totaling \$3.0 million in 2003 and four installments totaling \$3.0 million in 2004.

In April 2003, we entered into a Securities Purchase Agreement with Pharmion to acquire, for a total purchase price of \$12 million (i) \$12.0 million principal amount of 6.0% Senior Convertible Promissory Note due 2008 (the "Note") and (ii) a five-year warrant to purchase up to 363,636 shares of common stock of Pharmion, each convertible into shares of common stock of Pharmion at a purchase price of \$11.00 per share, which was subsequently adjusted for Pharmion's one-for-four reverse stock split. The Note was automatically convertible into common stock under certain conditions. In March 2004, we converted the Note (with accrued interest of approximately \$0.7 million) into 1,150,511 shares of Pharmion common stock. In addition, in September 2004, we exercised certain warrants that we had received in connection with both the November 2001 thalidomide license and the Securities Purchase Agreement for an aggregate of 789,089 shares of common stock of Pharmion. At December 31, 2004 we held 1,939,600 shares of Pharmion common stock.

In December 2004, following our acquisition of Penn T Limited, we expanded our THALOMID(R) development and commercialization collaboration with Pharmion. Pursuant to an amended thalidomide supply agreement with Pharmion, we received a one-time payment of \$77.0 million in exchange for a substantial reduction in Pharmion's purchase price of thalidomide. In addition, Pharmion has agreed to fund us an aggregate of \$10.0 million (including amounts remaining under the initial 2003 clinical trials agreement) from January 2005 to December 2007 to extend the two companies' April 2003 thalidomide development collaboration. We also received a one-time payment of \$3.0 million in return for granting license rights to Pharmion to develop and market thalidomide in three additional Asian territories (Hong Kong, Korea and Taiwan) and eliminating certain of our license termination rights.

#### MANUFACTURING

The bulk active pharmaceutical ingredient, or API, for THALOMID(R) is manufactured by ChemSyn Laboratories, a Division of Eagle-Picher Technologies, L.L.C., which operates a FDA cGMP-approved facility. (cGMP, or current Good Manufacturing Practices, are regulations established by the FDA that govern the manufacturing, processing, packaging, storing and testing of drugs intended for human use). The bulk drug substance is shipped to Celgene UK Manufacturing II Ltd., which contracts with Penn

Pharmaceuticals Services Limited of Great Britain to formulate and encapsulate THALOMID(R) for us in an FDA cGMP-approved facility. In October 2003, we signed an agreement with Institute of Drug Technology Australia Limited, or IDT, for the second-source manufacture of finished dosage form of THALOMID(R) capsules. The agreement is scheduled to commence with the FDA's approval of IDT's facility. The agreement provides us with additional capacity and reduces our dependency on one manufacturer for the formulation and encapsulation of THALOMID(R). In certain instances, we may be required to make substantial capital expenditures to access additional manufacturing capacity.

The bulk API for REVLIMID(R) is manufactured by Evotec OAI, Ltd. under a supply agreement entered into in August 2004. We contracted with Penn Pharmaceuticals Services Ltd. in September 2004 for the formulation and encapsulation of REVLIMID(R) in different dosage forms. We also entered into a contract manufacturing agreement with OSG Norwich Pharmaceuticals, Inc. in April 2004 as a second source for the formulation, encapsulation and packaging of REVLIMID(R) in different dosage forms. We plan to construct and operate our own manufacturing facility to produce and supply REVLIMID(R) for commercial sale in the United States, Europe and potentially in other geographic markets.

The bulk API for FOCALIN(R) and FOCALIN(R) XR is manufactured and supplied by Johnson Matthey Inc. A Supply Agreement was executed in March 2003 with a second supplier, Siegfried USA Inc. The product is manufactured into finished dosage forms of different strengths and packaged as FOCALIN(R) tablets by Mikart, Inc. for distribution.

#### INTERNATIONAL EXPANSION

In November 2001, we signed agreements with Pharmion Corporation and Penn Pharmaceuticals Services Limited to expand the THALOMID(R) franchise in all countries outside North America, Japan, China, Taiwan and Korea. The strategic partnership combined Penn's FDA-compliant manufacturing capability, Pharmion's global development and marketing expertise and our intellectual property. The alliance was designed to accelerate the establishment of THALOMID(R) as an important therapy in the international markets. To date, Pharmion has received regulatory approval in Australia, New Zealand, Turkey and Israel to market and distribute Thalidomide for the treatment of multiple myeloma after the failure of standard therapies, as well as for the treatment of complications of leprosy. In October 2004, we acquired Penn T Limited, a worldwide supplier of THALOMID(R). Through manufacturing contracts acquired in this acquisition, we are able to control manufacturing for THALOMID(R) worldwide and we also increased our participation in the potential sales growth of THALOMID(R) in key international markets. In December 2004, we amended several agreements with Pharmion including a collaborative R&D agreement and a manufacturing supply agreement, as well as the License agreement signed in November 2001, which added to the territories licensed in that agreement. In December 2003, we established a legal entity in Switzerland where we are developing a facility to perform formulation, encapsulation, packaging, warehousing and distribution of future products.

## SALES AND COMMERCIALIZATION

We have a 197-person U.S. pharmaceutical commercial organization. These individuals have considerable experience in the pharmaceutical industry, and many have experience with oncological and immunological products. We expect to expand our sales and commercialization group to support products we develop to treat oncological and immunological diseases. We intend to market and sell the products we develop for indications with accessible patient populations. For drugs with indications involving larger patient populations, we may partner with other pharmaceutical companies. In addition, we are positioned to accelerate the expansion of these sales and marketing resources as appropriate to take advantage of product in-licensing and product acquisition opportunities.

## EMPLOYEES

As of March 1, 2005, we had 766 full-time employees, 432 of who were engaged primarily in research and development activities, 204 (including CCT) who were engaged in sales and commercialization activities and the remainder of who were engaged in executive and general and administrative activities. We also maintain consulting arrangements with a number of researchers at various universities and other research institutions in Europe and the United States.

## FORWARD-LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this annual report are forward-looking statements concerning our business, financial condition, results of operations, economic performance and financial condition. Forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and within the meaning of Section 21E of the Securities Exchange Act of 1934 are included, for example, in the discussions about:

- o our strategy;
- o new product discovery, development or product introduction;
- o product manufacturing
- o product sales, royalties and contract revenues;
- o expenses and net income;
- o our credit risk management;
- o our liquidity;
- o our asset/liability risk management; and
- o our operational and legal risks.

These statements involve risks and uncertainties. Actual results may differ materially from those expressed or implied in those statements. Factors that could cause such differences include, but are not

limited to, those discussed under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

#### RISK FACTORS

##### WE HAVE A HISTORY OF OPERATING LOSSES AND AN ACCUMULATED DEFICIT

Until 2003, we had sustained losses in each year since our incorporation in 1986. For the years ended December 31, 2004 and December 31, 2003, we posted net income of \$52.8 million and \$25.7 million, respectively. In addition, we had an accumulated deficit of \$234.4 million at December 31, 2004. We expect to make substantial expenditures to further develop and commercialize our products. We also expect that our rate of spending will accelerate as the result of increased clinical trial costs and expenses associated with regulatory approval and commercialization of products now in development.

IF WE ARE UNSUCCESSFUL IN DEVELOPING AND COMMERCIALIZING OUR PRODUCTS, OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS COULD BE MATERIALLY ADVERSELY AFFECTED WHICH COULD IMPACT NEGATIVELY ON THE VALUE OF OUR COMMON STOCK.

Many of our products and processes are in the early or mid-stages of research and development and will require the commitment of substantial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. With the exception of FOCALIN(R), ALKERAN(R), THALOMID(R), AMBIODRY(TM) and BIOVANCE(TM), all of our other products will require further development, clinical testing and regulatory approvals before initial commercial marketing in the United States and internationally. If it becomes too expensive to sustain our present commitment of resources on a long-term basis, we will be unable to continue our necessary research and development activities. Furthermore, we cannot be certain that our clinical testing will render satisfactory results, or that we will receive required regulatory approval for our products. If any of our products, even if developed and approved, cannot be successfully commercialized, our business, financial condition and results of operations could be materially adversely affected which could impact negatively on the value of our common stock.

DURING THE NEXT SEVERAL YEARS, WE WILL BE VERY DEPENDENT ON THE COMMERCIAL SUCCESS OF THALOMID(R), ALKERAN(R), FOCALIN(R), AND THE ENTIRE RITALIN(R) PRODUCT LINE.

At our present level of operations, we may not be able to maintain profitability if physicians prescribe THALOMID(R) only for patients who are diagnosed with ENL. ENL, a complication of leprosy, is a chronic bacterial disease. Under current FDA regulations, we are precluded from promoting THALOMID(R) outside this approved use. The market for the use of THALOMID(R) in patients suffering from ENL is relatively small. We have conducted clinical studies designed to show that THALOMID(R) is active when used to treat disorders other than ENL, such as multiple myeloma, but we do not know whether we will succeed in receiving regulatory approval to market THALOMID(R) for such indications. FDA regulations place restrictions on our ability to communicate the results of additional clinical studies to patients and physicians without first obtaining approval from the FDA to expand the authorized uses for this product. In addition, if adverse experiences are reported in connection with the use of THALOMID(R) by patients, this could undermine physician and patient comfort with the product, could limit the commercial success of the product and could even impact the acceptance of THALOMID(R) in the ENL market. We are dependent upon royalties from Novartis Pharma AG's entire RITALIN(R) product line, including FOCALIN(R), although we cannot directly impact their ability to successfully commercialize these products. We have annual minimum purchase requirements relating to ALKERAN(R)



through March 31, 2006, which we license from GlaxoSmithKline. Additionally, our revenues would be negatively impacted if generic versions of any of these products were to be approved and launched.

WE FACE THE RISK OF PRODUCT LIABILITY CLAIMS AND MAY NOT BE ABLE TO OBTAIN SUFFICIENT INSURANCE ON COMMERCIALLY REASONABLE TERMS OR WITH ADEQUATE COVERAGE.

We may be subject to a variety of types of product liability or other claims based on allegations that the use of our technology or products has resulted in adverse effects, whether by participants in our clinical trials, by patients using our products or by other persons exposed to our products. Thalidomide, when used by pregnant women, has resulted in serious birth defects. Therefore, necessary and strict precautions must be taken by physicians prescribing the drug to women with childbearing potential. These precautions may not be observed in all cases or, if observed, may not be effective. Use of thalidomide has also been associated, in a limited number of cases, with other side effects, including nerve damage. Although we have product liability insurance that we believe is appropriate, we may be unable to maintain existing coverage or obtain additional coverage on commercially reasonable terms if required, or our coverage may be inadequate to protect us in the event of a multitude of claims being asserted against us. Our obligation to defend against or pay any product liability or other claim may be expensive and divert the efforts of our management and technical personnel.

IF OUR PRODUCTS ARE NOT ACCEPTED BY THE MARKET, DEMAND FOR OUR PRODUCTS WILL DETERIORATE OR NOT MATERIALIZE AT ALL.

It is necessary that our, and our distribution partner's products, including THALOMID(R), ALKERAN(R) and FOCALIN(R), achieve market acceptance. A number of factors can render the degree of market acceptance of our products uncertain, including the products' efficacy, safety and advantages, if any, over competing products, as well as the reimbursement policies of third-party payors, such as government and private insurance plans. In particular, thalidomide, when used by pregnant women, has resulted in serious birth defects, and the negative history associated with thalidomide and birth defects may decrease the market acceptance of THALOMID(R). In addition, the products that we are attempting to develop through our Celgene Cellular Therapeutics subsidiary may represent substantial departures from established treatment methods and will compete with a number of traditional drugs and therapies which are now, or may be in the future, manufactured and marketed by major pharmaceutical and biopharmaceutical companies. Furthermore, public attitudes may be influenced by claims that stem cell therapy is unsafe, and stem cell therapy may not gain the acceptance of the public or the medical community. If our products are not accepted by the market, demand for our products will deteriorate or not materialize at all.

WE MAY EXPERIENCE SIGNIFICANT FLUCTUATIONS IN OUR QUARTERLY OPERATING RESULTS.

We have historically experienced, and expect to continue for the foreseeable future to experience, significant fluctuations in our quarterly operating results. These fluctuations are due to a number of factors, many of which are outside our control, and may result in volatility of our stock price. Future operating results will depend on many factors, including:

- o demand for our products;
- o regulatory approvals for our products;
- o reimbursement from third party payors for our products;
- o the timing of the introduction and market acceptance of new products by us or competing companies;

- o the timing and recognition of certain research and development milestones and license fees; and
- o our ability to control our costs.

WE HAVE NO U.S. COMMERCIAL MANUFACTURING FACILITIES AND WE ARE DEPENDENT ON ONE SUPPLIER FOR THE RAW MATERIAL OF THALOMID(R) AND ARE DEPENDENT ON TWO SUPPLIERS FOR THE RAW MATERIAL AND ONE MANUFACTURER FOR THE TABLETING AND PACKAGING OF FOCALIN(R)

We currently have no U.S. facilities for manufacturing any products on a commercial scale. The bulk drug material for THALOMID(R) is manufactured by ChemSyn Laboratories, a Division of Eagle-Picher Technologies, L.L.C. We currently obtain all of our bulk active pharmaceutical ingredient for FOCALIN(R) from two suppliers, Johnson Matthey Inc. and Seigfried USA, Inc., and we rely on a single manufacturer, Mikart, Inc., for the packaging and tableting of FOCALIN(R).

On October 21, 2004, we acquired all of the outstanding shares of Penn T Limited, the UK-based manufacturer of THALOMID(R), which subsequently became known as Celgene UK Manufacturing II, Limited (or CUK II). In connection with the acquisition, we and CUK II entered into a Technical Services Agreement with Penn Pharmaceuticals Services Limited (PPSL), pursuant to which PPSL provides the services and facilities necessary for the manufacture of our requirements of THALOMID(R) and other thalidomide formulations. In addition, we have signed an agreement with the Institute of Drug Technology Australia Limited ( IDT) for the manufacture of finished dosage form of THALOMID capsules. The agreement is scheduled to commence with the FDA's approval of IDT's facility, which we anticipate to occur in the second half of 2005.

Presently, we are actively seeking alternative sources to each of Mikart and PPSL, including our arrangements with IDT. The FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's cGMP regulations and guidelines. If the operations of either Mikart or PPSL were to become unavailable for any reason (and/or if the FDA's approval of IDT's facility was either delayed or denied for any reason), any required FDA review and approval of the operations of an alternative could cause a delay in the manufacture of THALOMID(R) or FOCALIN(R). In addition, although we have now acquired the THALOMID(R) manufacturing operations of CUK II, we intend to continue to utilize outside manufacturers if and when needed to produce certain of our other products on a commercial scale. If our outside manufacturers do not meet our requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline, to the extent we depend on these outside manufacturers.

WE HAVE LIMITED MARKETING AND DISTRIBUTION CAPABILITIES.

Although we have a 197-person U.S. pharmaceutical commercial organization to support our products, we may be required to seek one or more corporate partners to provide marketing services with respect to our other products. Any delay in developing these resources could substantially delay or curtail the marketing of these products. We have contracted with Ivers Lee Corporation, d/b/a Sharp, a specialty distributor, to distribute THALOMID(R). If Sharp does not perform its obligations, our ability to distribute THALOMID(R) may be severely restricted.

WE ARE DEPENDENT ON COLLABORATIONS AND LICENSES WITH THIRD PARTIES

Our ability to fully commercialize our products, if developed, may depend to some extent upon our entering into joint ventures or other arrangements with established pharmaceutical and biopharmaceutical

companies with the requisite experience and financial and other resources to obtain regulatory approvals and to manufacture and market such products. Our collaborations and licenses include an exclusive license (excluding Canada) to Novartis for the development and commercialization of FOCALIN(R) ("d-MPH"); an agreement with Biovail Corporation International, wherein we granted to Biovail exclusive Canadian marketing rights for d-MPH; and an agreement with Pharmion Corporation to expand the THALOMID(R) franchise internationally; and an agreement with GlaxoSmithKline to distribute, promote and sell ALKERAN(R). Our present and future arrangements may be jeopardized if any or all of the following occur:

- o we are not able to enter into additional joint ventures or other arrangements on acceptable terms, if at all;
- o our joint ventures or other arrangements do not result in a compatible working relationship;
- o our joint ventures or other arrangements do not lead to the successful development and commercialization of any products;
- o we are unable to obtain or maintain proprietary rights or licenses to technology or products developed in connection with our joint ventures or other arrangements; or
- o we are unable to preserve the confidentiality of any proprietary rights or information developed in connection with our joint ventures or other arrangements.

THE HAZARDOUS MATERIALS WE USE IN OUR RESEARCH AND DEVELOPMENT COULD RESULT IN SIGNIFICANT LIABILITIES THAT COULD EXCEED OUR INSURANCE COVERAGE AND FINANCIAL RESOURCES.

We use some hazardous materials in our research and development activities. While we believe we are currently in substantial compliance with the federal, state and local laws and regulations governing the use of these materials, we cannot be certain that accidental injury or contamination will not occur. Any such accident or contamination could result in substantial liabilities that could exceed our insurance coverage and financial resources. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, requiring us to expend more financial resources either in compliance or in purchasing supplemental insurance coverage.

THE PHARMACEUTICAL INDUSTRY IS SUBJECT TO EXTENSIVE GOVERNMENT REGULATION, WHICH PRESENTS NUMEROUS RISKS TO US.

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. If we or our contractors and collaborators are delayed in receiving, or are unable to obtain at all, necessary governmental approvals, we will be unable to effectively market our products.

The testing, marketing and manufacturing of our products require regulatory approval, including approval from the FDA and, in some cases, from the U.S. Environmental Protection Agency or governmental authorities outside of the United States that perform roles similar to those of the FDA and EPA. Certain of our pharmaceutical products, such as FOCALIN(R), fall under the Controlled Substances Act of 1970 that requires authorization by the U.S. Drug Enforcement Agency, or DEA, of the U.S. Department of Justice in order to handle and distribute these products. The regulatory approval process presents several risks to us.

- o In general, preclinical tests and clinical trials can take many years, and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretation that could delay, limit or prevent regulatory approval;
- o Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, a regulatory agency's requirements for safety, efficacy and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first;
- o Requirements for approval may become more stringent due to changes in regulatory agency policy, or the adoption of new regulations or legislation;
- o The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and may impose significant limitations in the nature of warnings, precautions and contraindications that could materially affect the sales and profitability of the drug;
- o Approved drugs, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their manufacture, sale or use or in their withdrawal from the market;
- o Regulatory authorities and agencies may promulgate additional regulations restricting the sale of our existing and proposed products;
- o Once a product receives marketing approval, the FDA may not permit us to market that product for broader or different applications, or may not grant us approval with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing approvals in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products;
- o Our labeling and promotional activities relating to our products are regulated by the FDA and state regulatory agencies and, in some circumstances, by the DEA, and are subject to associated risks. If we fail to comply with FDA regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained, the FDA, or the Office of the Inspector General of the Department of Health and Human Services or the state Attorneys General could bring an enforcement action against us that could inhibit our marketing capabilities as well as result in significant penalties.

FDA's Center for Biologics Evaluation and Research currently regulates under 21 CFR Parts 1270 and 1271 human tissue intended for transplantation that is recovered, processed, stored or distributed by methods that do not change tissue function or characteristics and that is not currently regulated as a human drug, biological product or medical device. Certain stem cell activities fall within this category. Part 1270 requires tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease and to maintain records. It also provides for inspection by FDA of tissue establishments. Part 1271 requires human cells, tissue and cellular and tissue-based product establishments (HCT/PS) to register with the agency and list their HCT/PS

Currently, we are required to be, and are, licensed to operate in New York and New Jersey, two of the states in which we currently collect placentas and umbilical cord blood for our allogeneic and private stem cell banking businesses. If other states adopt similar licensing requirements, we would need to

obtain such licenses to continue operating. If we are delayed in receiving, or are unable to obtain at all, necessary licenses, we will be unable to provide services in those states which would impact negatively on our revenues.

WE MAY NOT BE ABLE TO PROTECT OUR INTELLECTUAL PROPERTY.

Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties, when necessary, and conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical firms, including ours, can be uncertain and involve complex legal and factual questions.

Under the current U.S. patent laws, patent applications in the United States are maintained in secrecy from six to eighteen months, and publications of discoveries in the scientific and patent literature often lag behind actual discoveries. Thus, we may discover sometime in the future, that we, or the third parties from whom we have licensed patents or patent applications, were not the first to make the inventions covered by the patents and patent applications in which we have rights, or that such patents and patent applications were not the first to be filed on such inventions. In the event that a third party has also filed a patent application for any of the inventions claimed in our patents or patent applications, or those we have licensed-in, we could become involved in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention. Such an interference could result in the loss of an issued U.S. patent or loss of any opportunity to secure U.S. patent protection for that invention. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us.

In addition, the coverage sought in a patent application may not be obtained or may be significantly reduced before the patent is issued. Consequently, if our pending applications, or a pending application that we have licensed-in from third parties, do not result in the issuance of patents or if any patents that are issued do not provide significant proprietary protection or commercial advantage, our ability to sustain the necessary level of intellectual property rights upon which our success depends may be restricted.

Furthermore, even if our patents, or those we have licensed-in, are issued, our competitors may still challenge the scope, validity or enforceability of our patents in court, requiring us to engage in complex, lengthy and costly litigation. Alternatively, our competitors may be able to design around such patents and compete with us using the resulting alternative technology. If any of our issued or licensed patents are infringed, we may not be successful in enforcing our intellectual property rights or defending the validity or enforceability of our issued patents.

Moreover, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensor, in a given country, of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in other countries may be limited.

On January 15, 2004, an opposition proceeding was brought by Celltech R&D Ltd. against granted European Patent 0728143 which we have licensed from the University of California relating to JNK 1 and JNK 2 polypeptides. This proceeding is directed to only the claims for JNK 2 and not JNK 1. We intend to respond to this proceeding. A decision on the merits is not expected until sometime in 2005 at the earliest

It is also possible that third-party patent applications and patents could issue with claims that cover certain aspects of our business or of the subject matter claimed in the patents owned or optioned by us or licensed to us, which may limit our ability to conduct our business or to practice under our patents, and may impede our efforts to obtain meaningful patent protection of our own. If patents are issued to third parties that contain competitive or conflicting claims, we may be legally prohibited from pursuing research, development or commercialization of potential products or be required to obtain licenses to these patents or to develop or obtain alternative technology. We may be legally prohibited from using patented technology, may not be able to obtain any license to the patents and technologies of third parties on acceptable terms, if at all, or may not be able to obtain or develop alternative technologies. Consequently, if we cannot successfully defend against any patent infringement suit that may be brought against us by a third party, we may lose the ability to continue to conduct our business as we presently do, or to practice certain subject matter delineated by patent claims that we have exclusive rights to, whether by ownership or by license, and that may have a material adverse effect on our business.

We rely upon trademarks and service marks to protect our rights to the intellectual property used in our business. On October 29, 2003, we filed a lawsuit against Centocor, Inc. to prevent Centocor's use of the term "I.M.I.D.s" in connection with Centocor's products, which use, we believe, is likely to cause confusion with our IMiDs mark for compounds being developed by us to treat cancer and inflammatory diseases. If we are not successful in this suit, it may be necessary for us to adopt a different trademark for that class of compounds and thereby lose the value we believe we have built in the IMiDs mark.

On August 19, 2004 we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court of New Jersey against Teva Pharmaceuticals USA, Inc., in response to notices of Paragraph IV certifications made by Teva in connection with the filing of an ANDA (Abbreviated New Drug Application) for d-methylphenidate immediate release (FOCALIN(R)). The notification letters contend that United States Patent Nos. 5,908,850, or 850 patent, and 6,355,656, or 656 patent, were invalid. The 656 patent is currently the subject of reexamination proceedings in the United States Patent and Trademark Office. After the suit was filed, Novartis listed another patent, United States Patent No. 6,528,530, or 530 patent, in the Orange Book in association with the FOCALIN(R) NDA. The 530 patent is currently not part of the Celgene v. Teva case. This case does not relate to RITALIN(R) LA or any other long acting formulation. Discovery is at the earliest stage. If successful, Teva will be permitted to sell a generic version of FOCALIN(R) immediate release.

Further, we rely upon unpatented proprietary and trade secret technology that we try to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. If these agreements are breached, we may not have adequate remedies for any such breach. Despite precautions taken by us, others may obtain access to or independently develop our proprietary technology or such technology may be found to be non-proprietary or not a trade secret.

In addition, our right to practice the inventions claimed in some patents that relate to THALOMID(R) arises under licenses granted to us by others, including The Rockefeller University and Children's Medical Center Corporation, or CMCC. In addition to these patents, which relate to thalidomide, we have also licensed from CMCC certain patents relating to thalidomide analogs. In December 2002, we entered into an exclusive license agreement with CMCC and EntreMed Inc. pursuant to which CMCC exclusively licensed to us certain patents and patent applications that relate to analogs, metabolites, precursors and hydrolysis products of thalidomide, and all stereoisomers thereof. Our license under the December 2002 agreement is worldwide and royalty-bearing, and we have complete control over the prosecution of the licensed thalidomide analog patent rights. The December 2002 agreement also grants us an option to inventions in the field of thalidomide analogs that may be developed at CMCC in the laboratory of Dr. Robert D'Amato, pursuant to the terms and conditions of a separate Sponsored Research Agreement negotiated between CMCC and us.

Further, while we believe these confidentiality and license agreements to be valid and enforceable, our rights under these agreements may not continue or disputes concerning these agreements may arise. If any of the foregoing should occur, we may be unable to rely upon our unpatented proprietary and trade secret technology, or we may be unable to use the third-party proprietary technology we have licensed-in, either of which may prevent or hamper us from successfully pursuing our business.

The orphan drug exclusivity for thalidomide expires on July 16, 2005. Generic drug companies can file an abbreviated new drug application, or ANDA to seek approval to market thalidomide in the United States. However, such an ANDA filer will need to challenge the validity or enforceability of our United States patents relating to our S.T.E.P.S.(R) program or to demonstrate that they do not use an infringing risk management program. We cannot predict whether an ANDA challenge to our patents will be made, nor can we predict whether our S.T.E.P.S.(R) patents can be circumscribed or invalidated or otherwise rendered unenforceable.

THE PHARMACEUTICAL INDUSTRY IS HIGHLY COMPETITIVE AND SUBJECT TO RAPID AND SIGNIFICANT TECHNOLOGICAL CHANGE.

The pharmaceutical industry in which we operate is highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms, such as:

- o Bristol Myers Squibb Co., which potentially competes in clinical trials with our IMiDs and PDE4 inhibitors;
- o Genentech Inc., which potentially competes in clinical trials with our IMiDs and PDE4 inhibitors;
- o AstraZeneca p.l.c., which potentially competes in clinical trials with our IMiDs and PDE4 inhibitors;
- o ICOS Corporation which potentially competes in clinical trials with our PDE4 inhibitors;
- o Millennium Pharmaceuticals, which potentially competes in clinical trials with our IMiDs and PDE4 inhibitors as well as with THALOMID(R);
- o Cell Therapeutics Inc., which potentially competes in clinical trials with our IMiDs and THALOMID(R);
- o Vertex Pharmaceuticals Inc. and Pfizer which potentially competes in clinical trials with our kinase inhibitors; and
- o Biogen IDEC Inc. and Genzyme Corporation both of which are generally developing drugs that address the oncology and immunology markets, although we are not aware of specific competing products.

Many of these companies have considerably greater financial, technical and marketing resources than we. We also experience competition from universities and other research institutions and, in some instances, we compete with others in acquiring technology from these sources. The pharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances in the field are made and become more widely known. The development of products or processes by our competitors with significant advantages over those that we are seeking to develop could cause the marketability of our products to stagnate or decline.

SALES OF OUR PRODUCTS ARE DEPENDENT ON THIRD-PARTY REIMBURSEMENT.

Sales of our products will depend, in part, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. These health care management organizations and third-party payors are increasingly

challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. If these organizations and third-party payors do not consider our products to be cost-effective or competitive with other available therapies, they may not reimburse providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

THE PRICE OF OUR COMMON STOCK MAY FLUCTUATE SIGNIFICANTLY, WHICH MAY MAKE IT DIFFICULT FOR YOU TO SELL THE COMMON STOCK WHEN YOU WANT OR AT PRICES YOU FIND ATTRACTIVE

There has been significant volatility in the market prices for publicly traded shares of biopharmaceutical companies, including ours. We expect that the market price of our common stock will continue to fluctuate. After adjusting prices to reflect our two-for-one stock split effected on October 22, 2004, the intra-day price of our common stock fluctuated from a high of \$32.58 to a low of \$18.74 in 2004. On March 11, 2005 our common stock closed at a price of \$32.80. The price of our common stock may not remain at or exceed current levels. The following key factors may have an adverse impact on the market price of our common stock:

- o results of our clinical trials,
- o announcements of technical or product developments by our competitors;
- o market conditions for pharmaceutical and biotechnology stocks;
- o market conditions generally;
- o governmental regulation;
- o health care legislation;
- o public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- o patent or proprietary rights developments;
- o changes in third-party reimbursement policies for our products, or
- o fluctuations in our operating results

In addition, the stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of a particular company. These broad market fluctuations may adversely affect the market price of our common stock.

THE NUMBER OF SHARES OF OUR COMMON STOCK ELIGIBLE FOR FUTURE SALE WOULD DILUTE THE OWNERSHIP INTEREST OF EXISTING STOCKHOLDERS AND COULD ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock. As of March 1, 2005, there were outstanding stock options and warrants for 25,186,118 shares of common stock, of which 24,567,768 were currently exercisable at an exercise price range between \$0.07 and \$35.00, with a weighted average exercise price of \$15.00. These amounts include outstanding options and warrants of Anthrogenesis (which is now our Celgene Cellular Therapeutics



subsidiary) that we assumed as part of our acquisition of Anthrogenesis on December 31, 2002 and that were converted into outstanding options and warrants of our common stock pursuant to an exchange ratio. In addition, in June 2003, we issued \$400.0 million of unsecured convertible notes that are convertible into 16,511,840 shares of our common stock at a conversion price of approximately \$24.225 per share. The conversion of some or all of these notes, if it occurs, will dilute the ownership interest of existing stockholders.

OUR SHAREHOLDER RIGHTS PLAN AND CERTAIN CHARTER AND BY-LAW PROVISIONS MAY DETER A THIRD PARTY FROM ACQUIRING US AND MAY IMPEDE THE STOCKHOLDERS' ABILITY TO REMOVE AND REPLACE OUR MANAGEMENT OR BOARD OF DIRECTORS.

Our board of directors has adopted a shareholder rights plan, the purpose of which is to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to all of our stockholders. The rights plan may have the effect of dissuading a potential acquirer from making an offer for our common stock at a price that represents a premium to the then current trading price.

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5,000,000 shares of preferred stock, and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third party from acquiring a majority of our outstanding voting stock. Additionally, our board of directors has adopted certain amendments to our by-laws intended to strengthen the board's position in the event of a hostile takeover attempt. These provisions could impede the stockholders' ability to remove and replace our management and/or board of directors.

Furthermore, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

#### AVAILABLE INFORMATION

Our current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K are electronically filed with the Securities and Exchange Commission, or SEC, and all such reports and amendments to such reports filed have been and will be made available, free of charge, through our website ([HTTP //WWW.CELGENE.COM](http://WWW.CELGENE.COM)) as soon as reasonably practicable after such filing. Such reports will remain available on our website for at least twelve months. The contents of our website are not incorporated by reference into this annual report. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, D.C.

The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

#### ITEM 2. PROPERTIES

We currently lease an aggregate of 92,100-square feet of laboratory and office space in Warren, New Jersey, under various leases with unaffiliated parties, which have lease terms ending between June 2005 and July 2010 with renewal options ranging from either one or two additional five-year terms. Annual rent for these facilities is approximately \$1.0 million. We also are required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. We also lease an 18,000-square foot laboratory and office facility in North Brunswick, New Jersey under a lease with an

unaffiliated party that has a term ending in March 2009 with two five-year renewal options. Annual rent for this facility is approximately \$0.5 million.

In November 2004, we purchased approximately 45 acres of land and several buildings located in Summit, New Jersey at a cost of \$25.0 million. The purchase of this site enables us to consolidate four New Jersey locations into one corporate headquarters and provide the space needed to accommodate the Company's expected growth. As a result, the Company is currently exploring available options to reduce or eliminate the financial impact of existing lease commitments on redundant facilities.

In December 2001, we entered into a lease to consolidate our San Diego, California operations into one building. The 78,202-square foot laboratory and office facility in San Diego, California was leased from an unaffiliated party and has a term ending in August 2012 with one five-year renewal option. Annual rent for this facility is approximately \$1.9 million and is subject to specified annual rental increases. Under the lease, we also are required to reimburse the lessor for real estate taxes, insurance, utilities, maintenance and other operating costs.

Upon completion of the acquisition of Anthrogenesis Corp. on December 31, 2002, we assumed two separate leases in the same facility for office and laboratory space in Cedar Knolls, New Jersey and have subsequently entered into one additional lease for additional space in the same facility. The leases are for an aggregate 20,000-square feet with annual rent of approximately \$0.2 million. We also are required to reimburse the lessor for real estate taxes, insurance, utilities, maintenance and other operating costs. The leases have terms ending between September 2007 and April 2009 with renewal options ranging from either one or two additional five-year terms. In November of 2002, Anthrogenesis entered into a lease for an additional 11,000 square feet of laboratory space in Baton Rouge, Louisiana. The lease has a five-year term with a three-year renewal option. Annual rent for this facility is approximately \$0.1 million.

#### ITEM 3. LEGAL PROCEEDINGS

We are not engaged in any material legal proceedings.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the NASDAQ National Market under the symbol "CELG." The following table sets forth, for the periods indicated, the intra-day high and low bid prices per share of common stock on the NASDAQ National Market (as adjusted for the two-for-one stock split affected on October 22, 2004):

	HIGH	LOW
2004		
Fourth Quarter	\$32.58	\$25.75
Third Quarter	30.09	23.33
Second Quarter	30.30	22.50
First Quarter	24.46	18.74
2003		
Fourth Quarter	\$24.08	\$18.26
Third Quarter	24.44	14.26
Second Quarter	18.57	12.36
First Quarter	13.98	10.08

The last reported sales price per share of common stock on the NASDAQ National Market on March 11, 2005 was \$32.80. As of February 24, 2005, there were approximately 40,518 holders of record of our common stock.

#### DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings for funding growth and, therefore, do not anticipate paying any cash dividends on our common stock in the foreseeable future.

# EQUITY COMPENSATION PLAN INFORMATION

The following table summarizes the equity compensation plans under which our common stock may be issued as of December 31, 2004:

PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (A)	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (B)	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS, EXCLUDING SECURITIES REFLECTED IN COLUMN (A) (C)
Equity compensation plans approved by security holders	23,936,754	\$15.51	1,823,735
Equity compensation plans not approved by security holders	1,539,256	\$ 8.15	97,664
Total	25,476,010	\$15.07	1,921,399

The Anthrogenesis Corporation Qualified Employee Incentive Stock Option Plan has not been approved by our stockholders. As a result of the acquisition of Anthrogenesis on December 31, 2002, we acquired the Anthrogenesis Qualified Employee Incentive Stock Option Plan, or the Qualified Plan, and the Non-Qualified Recruiting and Retention Stock Option Plan, or the Non-Qualified Plan. No future awards will be granted under the Non-Qualified Plan. The Qualified Plan authorizes the award of incentive stock options, which are stock options that qualify for special federal income tax treatment. The exercise price of any stock option granted under the Qualified Plan may not be less than the fair market value of the common stock on the date of grant. In general, options granted under the Anthrogenesis Qualified Plan vest evenly over a four-year period and expire ten years from the date of grant, subject to earlier expiration in case of termination of employment. The vesting period is subject to certain acceleration provisions if a change in control occurs. No award will be granted under the Qualified Plan on or after December 31, 2008.

## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report. The data set forth below with respect to our Consolidated Statement of Operations for the year ended December 31, 2004 and the Consolidated Balance Sheet data as of December 31, 2004 are derived from our Consolidated Financial Statements which have been audited by KPMG LLP, independent registered public accounting firm, and which are included elsewhere in this Annual Report and are qualified by reference to such Consolidated Financial Statements and related Notes thereto. The data set forth below with respect to our Consolidated Statements of Operations for the years ended December 31, 2003 and 2002 and the Consolidated Balance Sheets data as of December 31, 2003 and 2002 have been restated to reflect adjustments to the original filings that are discussed further in Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 2 of the Notes to the Consolidated Financial Statements which are included elsewhere in this Annual Report and are qualified by reference to such Consolidated Financial Statements and related Notes thereto. The data set forth

below with respect to our Consolidated Statements of Operations for the years ended December 31, 2001 and 2000 and the Consolidated Balance Sheets data as of December 31, 2001 and 2000 are derived from our Consolidated Financial Statements, which have been audited by KPMG LLP and which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

IN THOUSANDS, EXCEPT PER SHARE DATA	YEARS ENDED DECEMBER 31,				
	2004	2003	2002	2001	2000
		As restated	As restated		
CONSOLIDATED STATEMENTS OF OPERATIONS DATA:					
Total revenue	\$ 377,502	\$ 271,475	\$ 135,746	\$ 114,243	\$ 84,908
Costs and operating expenses	334,774	274,124	250,367	139,186	119,217
Other income (expense), net	20,443	28,310	23,031	20,807	15,496
Income tax provision (benefit)	10,415	718	(98)	(1,232)	(1,810)
Income (loss) from continuing Operations	52,756	24,943	(91,492)	(2,904)	(17,003)
Discontinued operations:					
Gain on sale of chiral assets	--	750	1,000	992	719
Net income (loss) applicable to common stockholders	\$ 52,756	\$ 25,693	\$ (90,492)	\$ (1,912)	\$ (16,284)
Income (loss) from continuing operations per common share(1)					
Basic	\$ 0.32	\$ 0.15	\$ (0.60)	\$ (0.02)	\$ (0.13)
Diluted	\$ 0.31	\$ 0.14	\$ (0.60)	\$ (0.02)	\$ (0.13)
Discontinued operations per common share(1)					
Basic	\$ --	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01
Diluted	\$ --	\$ 0.01	\$ 0.01	\$ 0.01	\$ 0.01
Net income (loss) applicable to common stockholders(1):					
Basic	\$ 0.32	\$ 0.16	\$ (0.59)	\$ (0.01)	\$ (0.12)
Diluted	\$ 0.31	\$ 0.15	\$ (0.59)	\$ (0.01)	\$ (0.12)
Weighted average number of shares of common stock outstanding (1):					
Basic	163,869	161,774	154,674	150,216	133,196
Diluted	172,855	170,796	154,674	150,216	133,196

(1) Amounts have been adjusted for the two-for-one stock split affected in October 2004 and the three-for-one stock split affected in April 2000.

IN THOUSANDS	YEARS ENDED DECEMBER 31,				
	2004	2003	2002	2001	2000
		As restated	As restated		
CONSOLIDATED BALANCE SHEETS DATA					
Cash and cash equivalents, and marketable Securities	\$ 748,537	\$ 666,967	\$ 261,182	\$ 310,041	\$ 306,162
Total assets	1,107,293	813,026	336,795	353,982	346,726
Long-term obligations under capital leases and equipment notes payable	4	16	40	46	633
Convertible notes	400,000	400,000	--	11,714	11,714
Accumulated deficit	(234,410)	(287,166)	(312,859)	(222,367)	(220,455)
Stockholders' equity	477,444	331,744	281,814	310,425	295,533

# ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## INTRODUCTION

We are a multi-national integrated biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. Our lead product THALOMID(R) (thalidomide) is currently marketed for the treatment of erythema nodosum leprosum, or ENL. This product is more widely used off-label for treating multiple myeloma and other cancers. Over the past several years, THALOMID(R) net sales have grown rapidly. The sales growth of THALOMID(R) has enabled us to make substantial investments in research and development, which has resulted in a broad portfolio of drug candidates in our product pipeline. These include a pipeline of THALOMID(R) analogs known as IMiDs™. REVLIMID(R), one of our clinical-stage IMiDs, is now being tested in multiple cancer trials, including ongoing pivotal Phase III Special Protocol Assessment, or SPA, trials in multiple myeloma, or MM, and Phase II trials in myelodysplastic syndromes, or MDS, MDS with 5q deletion chromosomal abnormalities and MM that have the potential to result in FDA approval in late 2005 or early 2006. Given REVLIMID(R)'s safety and efficacy profile, its large sales potential and the cost efficiencies we can achieve from marketing REVLIMID(R) through our established sales force, we anticipate the approval and launch of REVLIMID(R), if it occurs, would result in increased revenue and earnings. We believe that the sales growth of THALOMID(R), the growth potential for REVLIMID(R), the depth of our product pipeline, and our strong balance sheet position, make us competitive within the biopharmaceuticals sector.

## RESTATEMENT

Following a review in December 2004 of our accounting treatment for the convertible preferred shares and warrants we received in connection with the December 31, 2002 litigation settlement and related agreements with EntreMed, Inc. and the Children's Medical Center Corporation, or CMCC, where in return for approximately \$26.8 million in cash we acquired all related EntreMed thalidomide analog patents, terminated the litigation and received preferred shares convertible into 16,750,000 shares of EntreMed common stock and warrants to purchase 7,000,000 shares of EntreMed common stock, it was determined that an adjustment to our consolidated financial statements was required for the years ended December 31, 2003 and 2002. For more information about the litigation settlement with EntreMed Inc. and related agreements see Note 5 to our consolidated financial statements.

At December 31, 2002, based on what we believed was the appropriate accounting treatment under generally accepted accounting principles, we wrote off the entire \$26.8 million relating to the convertible

preferred shares, the warrants and the litigation settlement and did not recognize any gains or losses on the warrants during 2003. This accounting treatment was based on multiple reasons including: (1) EntreMed's financial condition and its continuing losses; (2) the fact that we included the warrants along with the convertible preferred shares investment in applying the equity method of accounting, under which we wrote off the entire investment in December 2002; and (3) our concern over the fair value of the warrants given the significant number of shares underlying the warrants and, our concern about the inability to convert the underlying shares into cash (even if the warrants were to be net share settled) without significantly affecting EntreMed's stock price.

Upon further review of the warrant terms, as well as the accounting treatment prescribed under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", or SFAS 133, and related Derivative Implementation Group, or DIG, interpretations, we have concluded that the warrants should be accounted for as a derivative instrument and carried on the balance sheet at fair value, with changes in fair value recorded through earnings.

In addition we reviewed the impairment of the investment in the EntreMed voting preferred shares. We have concluded that the investment should not have been fully written down as of the date of the transaction. Accordingly we have restored the investment of \$4.4 million as of December 31, 2002 and reduced the net loss by a like amount. Under the equity method of accounting, we have recorded our share of the EntreMed losses in 2003 until the investment was written down to zero in the third quarter of 2003.

We have now restated our consolidated financial statements. The cumulative effect of the restatement through December 31, 2003 is an increase in other assets of \$21.7 million and a decrease in accumulated deficit of \$21.7 million. Equity losses in associated companies of \$4.4 million were recorded for the year ended December 31, 2003. Interest and other income increased by \$16.6 million for the year ended December 31, 2003 and litigation settlement and related agreements expense decreased by \$9.5 million for the year ended December 31, 2002. Previously reported diluted net earnings per share increased by \$0.07 and \$0.06 for the years ended December 31, 2003 and 2002, respectively. The restatement did not have any impact on previously reported total revenues, 2003 reported net cash flows or 2003 operating loss.

The following is a summary of the impact of the restatement on (i) our Consolidated Balance Sheet at December 31, 2003 and (ii) our Consolidated Statements of Operations for the years ended December 31, 2003 and 2002. In 2002 net cash provided by operating activities improved by \$9.5 million and net cash provided by investing activities decreased by \$9.5 million. The 2003 operating and investing cash flows were not impacted.

IN THOUSANDS, EXCEPT PER SHARE DATA	PREVIOUSLY REPORTED	ADJUSTMENTS	AS RESTATED
YEAR ENDED DECEMBER 31, 2003:			
Consolidated Statement of Operations:			
Interest and other income	\$ 21,795	\$ 16,574	\$ 38,369
Equity losses in associated companies	--	4,392	4,392
Income before income taxes	13,479	12,182	25,661
Income from continuing operations	12,761	12,182	24,943
Net income	13,511	12,182	25,693
Per share:			
Income from continuing operations per - Basic	0.08	0.07	0.15
Income from continuing operations per - Diluted	0.07	0.07	0.14
Net income - Basic	0.08	0.08	0.16
Net income - Diluted	0.08	0.07	0.15
Consolidated Balance Sheet:			
Other assets	\$ 32,506	\$ 21,690	\$ 54,196
Total assets	791,336	21,690	813,026
Accumulated deficit	(308,856)	21,690	(287,166)
Total stockholders' equity	310,054	21,690	331,744

YEAR ENDED DECEMBER 31, 2002:

Consolidated Statement of Operations:			
Litigation settlement and related agreements	\$ 32,212	\$ (9,508)	\$ 22,704
Total expenses	259,875	(9,508)	250,367
Operating loss	(124,129)	9,508	(114,621)
Loss before income taxes	(101,098)	9,508	(91,590)
Loss from continuing operations	(101,000)	9,508	(91,492)
Net loss	(100,000)	9,508	(90,492)
Per share:			
Loss from continuing operations - Basic	(0.65)	0.05	(0.60)
Loss from continuing operations - Diluted	(0.65)	0.05	(0.60)
Net loss - Basic	(0.65)	0.06	(0.59)
Net loss - Diluted	(0.65)	0.06	(0.59)

Refer to Note 20 to our consolidated financial statements (unaudited) of the Notes to the Consolidated Financial Statements for the impact of the restatement on the 2004 and 2003 quarterly information. In addition, certain prior year amounts in Notes 1, 3, 4, 5, 9, 17, 19 and 20 to our consolidated financial statements have been restated to reflect the restatement adjustments described above.

FACTORS AFFECTING FUTURE RESULTS

Future operating results will depend on many factors, including demand for our products, regulatory approvals of our products, the timing and market acceptance of new products launched by us or competing companies, the timing of research and development milestones, challenges to our intellectual property and our ability to control costs. The most salient factors are, in the near term, competition with



THALOMID(R), including generic competition, and delays in the introduction of REVLIMID(R) and, in the longer term, failure to commercialize our early-stage drug candidates.

NEAR-TERM COMPETITION WITH THALOMID(R): While we believe that THALOMID(R) will continue to be used as a treatment in multiple myeloma and that competing products will not eliminate its use, it is possible that competition could reduce THALOMID(R) sales in multiple myeloma. In addition, generic competition could reduce THALOMID(R) sales. However, we own intellectual property which includes, for example, numerous U.S. patents covering restrictive drug distribution systems for more safely delivering drugs, including our "System for Thalidomide Education and Prescribing Safety", or S.T.E.P.S.(R), distribution program, which all patients receiving thalidomide in the United States must follow and which are listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluation, or Orange Book. These patents do not expire until the years 2018-2020. We also have exclusive rights to several issued patents covering the use of THALOMID(R) in oncology. Even if generic competition were able to enter the market, it is unlikely such products could do so before 2007 based on a number of factors, including the time needed to commercialize such a product and the fact that challenges to THALOMID(R) will require a generic competitor to make a patent certification of non-infringement and/or invalidity of our patents listed in the Orange Book pursuant to the Federal Food, Drug and Cosmetic Act, which would then, in turn, entitle us up to a 30-month stay of market approval of that generic equivalent. By that time, we plan to have at least partially replaced THALOMID(R) sales with REVLIMID(R) sales. On October 22, 2004, we received an approvable letter from the FDA relating to our THALOMID(R) multiple myeloma supplemental new drug application, or sNDA. The FDA letter stated that sufficient support for an accelerated approval could be provided by the results of the completed Eastern Cooperative Oncology Group, or ECOG, study comparing thalidomide plus dexamethasone to dexamethasone alone in previously untreated multiple myeloma patients. The submission of this additional data and completion of required responses and its review by the FDA may result in an accelerated approval of THALOMID(R) as a treatment for multiple myeloma in the second half of 2005.

DELAY IN THE INTRODUCTION OF REVLIMID(R): While we have made progress toward regulatory approval of REVLIMID(R) based on ongoing pivotal Phase III Special Protocol Assessment, or SPA, trials for REVLIMID(R) in multiple myeloma, a delay in the introduction of REVLIMID(R) or its failure to demonstrate efficacy or an acceptable safety profile could adversely affect our business, consolidated financial condition and results of operations. Moreover, other factors such as the availability of FDA-approved competing products for the treatment of MDS could impact the market's acceptance of REVLIMID(R). In addition, our ongoing open label Phase II trials in MDS and multiple myeloma have completed their targeted enrollment. While the submission of an NDA based on data from these trials could result in an earlier regulatory approval if the data were to be sufficiently compelling, it should be noted that the FDA does not often grant approvals based on Phase II open label data alone.

FAILURE TO COMMERCIALIZE EARLY-STAGE DRUG CANDIDATES: Our long-term success and sustainability depends on our ability to advance our earlier-stage drug candidates through development and to realize the commercial potential of our broad product pipeline.

#### COMPANY BACKGROUND

In 1986, we were spun off from Celanese Corporation and in July 1987 we completed an initial public offering of our common stock. Initially, our operations involved research and development of chemical and biotreatment processes for the chemical and pharmaceutical industries. In 1994, we discontinued the biotreatment operations to focus on our programs for developing small molecule compounds for cancer and immunology indications, and on our biocatalytic chiral chemistry program.

Between 1990 and 1998, our revenues were derived primarily from the development and supply of chirally pure intermediates to pharmaceutical companies for use in new drug development. By 1998, sales of chirally pure intermediates became a less integral part of our strategic focus and, in January 1998 we sold the chiral intermediates business to Cambrex Corporation. Revenue from license agreements and milestone payments related to our cancer and immunology programs began to increase at this time.

In July 1998, we received approval from the FDA to market THALOMID(R) for use in ENL, a complication of the treatment of leprosy, and, in September 1998 we commenced sales of THALOMID(R) in the United States. Sales of THALOMID(R) have grown significantly each year, and THALOMID(R) has become our lead product. In 2002, 2003 and 2004 we recorded net THALOMID(R) sales of \$119.1 million, \$223.7 million and \$308.6 million, respectively.

In February 2000, we completed a follow-on public offering in which we raised proceeds, net of offering expenses, of approximately \$278.0 million. In April 2000, we signed a licensing and development agreement with Novartis Pharma AG in which we granted to Novartis a license for FOCALIN(R), our chirally pure version of RITALIN(R). The agreement provided for significant upfront and milestone payments to us based on the achievement of various stages in the regulatory approval process. It also provided for Celgene to receive royalties on the entire family of RITALIN(R) products. Pursuant to the agreement we retained the rights to FOCALIN(R) in oncology indications.

In August 2000, we acquired Signal Pharmaceuticals, Inc., a privately held biopharmaceutical company focused on the discovery and development of drugs that regulate genes associated with disease. In December 2002, we acquired Anthrogenesis Corp., a privately held biotherapeutics company developing processes for the recovery of stem cells from human placental tissue following the completion of a successful full-term pregnancy for use in stem cell transplantation, regenerative medicine and biomaterials for organ and wound repair.

In March 2003, we entered into a three-year supply and distribution agreement with GlaxoSmithKline, or GSK, to distribute, promote and sell ALKERAN(R), ormeluphalan, a therapy approved by the FDA for the palliative treatment of multiple myeloma and carcinoma of the ovary. The agreement, which provides us with an FDA approved oncology product, requires that we purchase ALKERAN(R) from GSK and distribute the products in the United States under the Celgene label. In June 2003, we raised an additional \$387.8 million, net of expenses, through the issuance of \$400.0 million of five-year unsecured convertible notes.

In October 2004, through an indirect wholly-owned subsidiary, we acquired all of the outstanding shares of Penn T Limited, or Penn T, a worldwide supplier of THALOMID(R), from a consortium of private investors for a US dollar equivalency of approximately \$117.4 million in cash, net of cash acquired and including working capital adjustments and total estimated transaction costs. Through manufacturing contracts acquired in this acquisition, we are now able to control manufacturing for THALOMID(R) worldwide and we also increased our participation in the potential sales growth of THALOMID(R) in key international markets. Following this acquisition, in December 2004 we revised the Pharmion product supply agreement acquired in the Penn T acquisition. Under the modified agreement, Pharmion paid us a one-time payment of \$77.0 million in return for a reduction in their total product supply purchase price from 28.0 percent of Pharmion's thalidomide net sales, including cost of goods to 15.5 percent of net sales. The collaboration also entails Pharmion paying us an additional \$8.0 million over the next three years to extend the two companies' existing thalidomide research and development efforts and a one-time payment of \$3.0 million for granting Pharmion license rights to develop and market thalidomide in three additional Asian territories (Hong Kong, Korea and Taiwan), as well as for eliminating termination rights held by Celgene tied to the regulatory approval of thalidomide in Europe in November 2006. In late

2004, we entered into an agreement providing manufacturers of isotretinoin (Acutane(R)) a non-exclusive license to our System for Thalidomide Education and Prescribing Safety, or S.T.E.P.S., patent portfolio. The manufacturers of isotretinoin have licensed these patents with the intention of implementing a new pregnancy risk management system to safely deliver isotretinoin in potentially high-risk patient populations

Until 2003, we had sustained losses in each year since our incorporation in 1986. For the years ended December 31, 2003 and 2004, we posted net income of \$25.7 million and \$52.8 million, respectively, and at December 31, 2004 we had an accumulated deficit of \$234.4 million. Since our inception, we have financed our working capital requirements primarily through product sales; public and private sales of our equity securities and debt; income earned from investment of the proceeds of such securities sales; and revenues from research contracts and license payments. We expect to make substantial additional expenditures to further develop and commercialize our products. We expect that our rate of spending will accelerate as a result of increases in clinical trial costs, expenses associated with regulatory approval and expenses related to commercialization of products currently in development. However, we anticipate these expenditures to be more than offset by increased product sales, royalties, revenues from various research collaborations and license agreements with other pharmaceutical and biopharmaceutical companies, and investment income.

#### RESULTS OF OPERATIONS -

FISCAL YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002

TOTAL REVENUE: Total revenue and related percentages for the years ended December 31, 2004, 2003 and 2002, were as follows:

(IN THOUSANDS \$)	2004	2003	2002	% CHANGE	
				2003 TO 2004	2002 TO 2003
Net product sales:					
THALOMID(R)	\$308,577	\$223,686	\$119,060	38.0%	87.9%
FOCALIN(R)	4,177	2,383	3,861	75.3%	(38.3%)
ALKERAN(R)	16,956	17,827	--	(4.9%)	N/A
Other	861	557	--	54.6%	N/A
Total net product sales	\$330,571	\$244,453	\$122,921	35.2%	98.9%
Collaborative agreements					
and other revenue	20,012	15,174	8,115	31.9%	87.0%
Royalty revenue	26,919	11,848	4,710	127.2%	151.5%
Total revenue	\$377,502	\$271,475	\$135,746	39.1%	100.0%

#### NET PRODUCT SALES:

2004 COMPARED TO 2003: THALOMID(R) net sales were higher in 2004, as compared to 2003, primarily due to price increases implemented in the second half of 2003 and in the first nine months of 2004. The total number of prescriptions, which increased approximately 9.4% from the prior year period, was offset by lower average daily doses. FOCALIN(R) net sales were higher in 2004, as compared to 2003, due to the timing of shipments to Novartis for their commercial distribution. ALKERAN(R) net sales were lower in 2004, as compared to 2003, due to supply disruptions earlier in the year, which lead to inconsistent supplies of ALKERAN(R) IV and consequently inconsistent end-market buying patterns. Other

net product sales consist of sales of dehydrated human amniotic membrane for use in ophthalmic applications, which are generated through our Stem Cell Therapies segment following the December 2002 acquisition of Anthrogenesis Corp.

2003 COMPARED TO 2002: THALOMID(R) net sales were higher in 2003, as compared to 2002, due to the combination of price increases and oncologists' expanded use of the product as a treatment for various types of cancers, especially first-line use in multiple myeloma. THALOMID(R) net sales in 2003 also benefited from the market introduction, during the first half of the year, of two new higher-strength formulations, which had higher per unit sales prices. FOCALIN(R) net sales were lower in 2003, as compared to 2002, due to the timing of shipments to Novartis for their commercial distribution. The ALKERAN(R) supply and distribution agreement with GSK was executed in March 2003. Accordingly, sales for this product are reflected only in the 2003 period. Other net product sales consist of sales of dehydrated human amniotic membrane for use in ophthalmic applications, which are generated through our Stem Cell Therapies segment

COLLABORATIVE AGREEMENTS AND OTHER REVENUE: Revenues from collaborative agreements and other sources in 2004 included a \$7.5 million payment received from Novartis related to their FOCALIN(R) XR NDA submission; approximately \$7.5 million related to the Pharmion collaboration agreements, primarily thalidomide research and development funding and S.T.E.P.S. licensing fees; approximately \$3.7 million of umbilical cord blood enrollment, collection and storage fees generated through our Stem Cell Therapies segment; \$0.5 million from S.T.E.P.S. use licensing fees; and approximately \$0.8 million from other miscellaneous research and development and licensing agreements. The 2003 period included approximately \$6.0 million related to the agreement to terminate the Gelclair™ co-promotion agreement between OSI Pharmaceuticals Inc. and Celgene; approximately \$4.3 million of thalidomide research and development funding and S.T.E.P.S. licensing fees received in connection with the Pharmion collaboration agreements; approximately \$1.3 million of reimbursements from Novartis for shipments of bulk raw material used in the formulation of FOCALIN(R) XR and utilized in clinical studies conducted by Novartis; approximately \$2.9 million of umbilical cord blood enrollment, collection and storage fees generated through our Stem Cell Therapies segment; and \$0.7 million from other miscellaneous research and development and licensing agreements. The 2002 period included approximately \$4.9 million for amortization of an up-front payment and a \$1.0 million milestone payment received from Novartis Pharma AG in connection with the SERM license agreement; \$1.2 million of licensing fees from Pharmion; and \$1.0 million of other milestone and other miscellaneous payments.

ROYALTY REVENUE: Royalty revenue reflects royalties received from Novartis on sales of their entire family of RITALIN(R) drugs. The increases in royalty revenue were due to increases in the royalty rate on both RITALIN(R) and RITALIN(R) LA as well as increases in RITALIN(R) LA sales by Novartis.

COST OF GOODS SOLD: Cost of goods sold and related percentages for the years ended December 31, 2004, 2003 and 2002 were as follows:

(IN THOUSANDS \$)	2004	2003	2002
Cost of goods sold	\$ 59,726	\$ 52,950	\$ 20,867
Increase from prior year	\$ 6,776	\$ 32,083	\$ 1,885
Percentage increase from prior year	12.8%	153.7%	9.9%
Percentage of net product sales	18.1%	21.7%	17.0%
=====			

2004 COMPARED TO 2003: Cost of goods sold increased in 2004 from 2003, primarily as a result of higher royalties on THALOMID(R), partially offset by lower ALKERAN(R) costs. As a percentage of net product sales, however, cost of goods sold decreased primarily due to lower ALKERAN(R) costs. Profit margins on THALOMID(R) remained flat, as the increase in cost of goods sold (resulting from higher royalties) were offset by higher net sales (which were due to price increases implemented in the second half of 2003 and in the first nine months of 2004).

2003 COMPARED TO 2002: Cost of goods sold increased in 2003 from 2002, primarily due to significant growth in THALOMID(R) sales volumes, higher royalties on THALOMID(R) product sales and the introduction of ALKERAN(R). Cost of goods sold also increased as a percentage of net product sales primarily because of the introduction of ALKERAN(R), which has a significantly higher cost structure than THALOMID(R). The increase in the percentage, however, was partially offset by higher gross profits on THALOMID(R) (due to price increases initiated during the year) and by lower sales of FOCALIN(R) (which also has a higher reported cost structure than THALOMID(R)).

RESEARCH AND DEVELOPMENT: Research and development expenses consist primarily of salaries and benefits, contractor fees (paid principally to contract research organizations to assist in our clinical development programs), costs of drug supplies for our clinical and preclinical programs, costs of other consumable research supplies, regulatory and quality expenditures and allocated facilities charges such as building rent and utilities.

Research and development expenses and related percentages for the years ended December 31, 2004, 2003 and 2002 were as follows:

(IN THOUSANDS \$)	2004	2003	2002
Research and development expenses	\$ 160,852	\$ 122,700	\$ 84,924
Increase from prior year	\$ 38,152	\$ 37,776	\$ 17,271
Percentage increase from prior year	31.1%	44.5%	25.5%
Percentage of total revenue	42.6%	45.2%	62.6%

2004 COMPARED TO 2003: Research and development expenses increased by \$38.2 million in 2004 from 2003, primarily due to increased spending in various late-stage regulatory programs. These included Phase II regulatory programs for REVLIMID(R) in MDS and MM, as well as ongoing REVLIMID(R) Phase III SPA trials in MM.

2003 COMPARED TO 2002: Research and development expenses increased in 2003 from 2002, primarily due to the initiation of several large studies related to our THALOMID(R) and REVLIMID(R) clinical programs in the second half of 2002.

Research and development expenses in 2004 consisted of approximately \$78.3 million spent on human pharmaceutical clinical programs; \$33.4 million spent on other human pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; \$40.6 million spent on biopharmaceutical discovery and development programs; and \$8.6 million spent on placental stem cell and biomaterials programs. These expenditures support multiple core programs, including THALOMID(R), REVLIMID(R), ACTIMID(TM), CC-11006, PDE4/TNF-alpha inhibitors, other investigational compounds, such as kinase inhibitors, benzopyrans, ligase inhibitors and tubulin inhibitors, and placental and cord blood derived stem cell programs. In 2003, approximately \$52.8 million was spent on human pharmaceutical clinical programs; \$29.2 million was spent on other human

pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs, \$33.7 million was spent on biopharmaceutical discovery and development programs; and \$7.0 million was spent on placental stem cell and biomaterials programs. In 2002, approximately \$27.4 million was spent on human pharmaceutical clinical programs; \$22.2 million was spent on other human pharmaceutical programs, including toxicology, analytical research and development, drug discovery, quality and regulatory affairs; \$32.3 million was spent on biopharmaceutical discovery and development programs; and \$3.0 million was spent on agro-chemical programs.

For information about the commercial and development status and target diseases of our drug compounds, refer to the product overview table contained in Part I,

Item I of this annual report.

In general, the estimated times to completion within the various stages of clinical development are as follows:

CLINICAL PHASE	ESTIMATED COMPLETION TIME
Phase I	1-2 years
Phase II	2-3 years
Phase III	2-3 years

Due to the significant risks and uncertainties inherent in preclinical testing and clinical trials associated with each of our research and development projects, the cost to complete such projects is not reasonably estimable. The data obtained from these tests and trials may be susceptible to varying interpretation that could delay, limit or prevent a project's advancement through the various stages of clinical development, which would significantly impact the costs incurred in completing a project.

**SELLING, GENERAL AND ADMINISTRATIVE:** Selling expenses consist primarily of salaries and benefits for sales and marketing and customer service personnel and other commercial expenses to support our sales force. General and administrative expenses consist primarily of salaries and benefits, outside services for legal, audit, tax and investor activities and allocations of facilities costs, principally for rent, utilities and property taxes.

Selling, general and administrative expenses and related percentages for the years ended December 31, 2004, 2003 and 2002 were as follows:

(IN THOUSANDS \$)	2004	2003	2002
Selling, general and administrative expenses	\$ 114,196	\$ 98,474	\$ 66,172
Increase from prior year	\$ 15,722	\$ 32,302	\$ 13,621
Percentage increase from prior year	16.0%	48.8%	25.9%
Percentage of total revenue	30.3%	36.3%	48.7%

2004 COMPARED TO 2003: Selling, general and administrative expenses increased by \$15.7 million in 2004 from 2003, as a result of an increase of approximately \$12.0 million in general administrative and medical affairs expenses primarily due to higher headcount-related expenses and an increase of approximately \$3.6 million in sales force expenses primarily due to the creation of a sales operations group. The sales operations group,

among other things, manages pricing and reimbursement, corporate accounts, customer service and government affairs, as well as sales fleet expenses.

2003 COMPARED TO 2002: Selling, general and administrative expenses increased in 2003 from 2002, primarily due to first-time expenses of approximately \$10.1 million related to our Stem Cell Therapies segment following the December 2002 acquisition of Anthrogenesis Corp ; an increase of approximately \$12.0 million in commercial expenses related to the expansion of the sales and marketing organization and an increase in customer service staff; and an increase of approximately \$10.0 million in general administrative and medical affairs expenses.

LITIGATION SETTLEMENT AND RELATED AGREEMENTS: On December 31, 2002, we entered into a series of agreements with EntreMed, Inc. and Children's Medical Center Corporation, or CMCC, terminating ongoing litigation relating to patents for thalidomide analogs and directly granting to us an exclusive license issued by CMCC for the rights to those patents. Under the terms of an asset purchase agreement with EntreMed, we paid EntreMed \$10.0 million for all thalidomide analog patents and associated clinical data and records, and the termination of any litigation surrounding those patents. Under the terms of a securities purchase agreement with EntreMed, we acquired from EntreMed 3,350,000 shares of Series A Convertible Preferred Stock and warrants to purchase an additional 7,000,000 common shares for an aggregate cash consideration of approximately \$16.8 million. The Series A Convertible Preferred Stock is convertible, at our option into an aggregate of 16,750,000 shares of common stock at an initial conversion price of \$1.00 per share provided, however, that the conversion price in effect from time to time shall be subject to certain adjustments. Dividends are payable prior and in preference to the declaration or payment of any dividend or distribution to the holders of common stock. We have the right to one vote for each share of Common Stock into which such share of Series A Convertible Preferred Stock could then be converted and with respect to such vote we have full voting rights and powers equal to the voting rights and powers of the holders of shares of Common Stock. After assessing the level of our ownership interest in EntreMed and the fact that EntreMed is a clinical-stage biopharmaceutical company engaged primarily in research and development activities with proposed products and research programs in the early stage of clinical development, a charge of \$7.2 million was recorded for in-process research and development. As restated, we ascribed a value of \$11.6 million to the convertible preferred stock of which \$4.4 million was recorded as an investment in associated companies at December 31, 2002.

The warrants have an exercise price of \$1.50 per share, vest after six months from the date of grant and expire after seven years from the date of grant. The warrants also include a net settlement feature and as discussed in Note 2, it was subsequently determined that they should be accounted for as a derivative. We ascribed a value of \$5.1 million to the warrants as of December 31, 2002, which represents their estimated fair value at such date.

We signed an exclusive license agreement with CMCC that terminated any existing thalidomide analog agreements between CMCC and EntreMed and directly granted to Celgene an exclusive worldwide license for the analog patents. We paid CMCC \$2.5 million in December 2002 and \$0.5 million in January 2004 under the agreement. Another \$2.0 million is payable between 2005 and 2006. The present value of these payments totaled \$4.7 million and was expensed in 2002. Additionally, we entered into a five year sponsored research agreement with CMCC whereby we have committed \$0.3 million per year in funding. Additional payments are possible under the agreement depending on the successful development and commercialization of thalidomide analogs.

We recorded a charge to earnings for the cost of these agreements and related expenses of \$22.7 million in 2002 including the write-down of the EntreMed Convertible Preferred Stock to our residual equity interest in EntreMed and certain legal expenses incurred in connection with the settlement.

ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT: On December 31, 2002, we completed the acquisition of Anthrogenesis Corp., which now operates as Celgene Cellular Therapeutics, for an aggregate purchase price of \$60.0 million. The acquisition was accounted for using the purchase method of accounting for business combinations, under which approximately \$55.7 million was allocated to IPR&D and charged to expense at the acquisition date. For more information on the Anthrogenesis acquisition, refer to Notes 3 and 19 of the Notes to our Consolidated Financial Statements

INTEREST AND OTHER INCOME: Interest and other income decreased approximately 21.8% to \$30.0 million in 2004 from \$38.4 million in 2003. The decrease was primarily due to changes in the fair value of the EntreMed warrants. In 2004, we recorded unrealized losses of \$1.9 million related to these warrants whereas, in 2003 we recorded unrealized gains of \$16.6 million. This reduction was partially offset by higher returns on our cash and marketable securities portfolio (which was largely due to higher average balances of cash and marketable securities as a result of the issuance of \$400 million of convertible notes, on June 3, 2003, as well as cash generated through operations) and foreign exchange gains. Interest and other income increased approximately 66.4% to \$38.4 million in 2003 from \$23.1 million in 2002. The increase was primarily due to unrealized gains of \$16.6 in the fair value of the EntreMed warrants partially offset by lower interest income as a result of lower interest rates in 2003.

EQUITY IN LOSSES OF ASSOCIATED COMPANIES: As restated (see further discussions contained in this Management's Discussion and Analysis of Financial Condition and Results of Operations and Footnote 2 of our consolidated financial statements), during 2003 under the equity method of accounting we recorded \$4.4 million for our share of the EntreMed losses.

INTEREST EXPENSE: Interest expense in 2004 was approximately \$9.6 million and includes twelve months of interest expense and amortization of debt issuance costs on the \$400 million of convertible notes issued on June 3, 2003. Interest expense in 2003 was approximately \$5.7 million and only includes seven months of interest expense and amortization of debt issuance costs on the \$400 million of convertible notes issued on June 3, 2003. Interest expense in 2002 was immaterial.

INCOME TAX BENEFIT (PROVISION): In 2004, we recorded an income tax provision of approximately \$10.4 million, which reflects an effective underlying tax rate of 16.5%. Our rate rose in 2004 from 2003 primarily due to federal tax expense and decreases in the valuation allowance available to offset income tax expense. In 2003, our income tax provision was approximately \$0.7 million and included income tax expense of \$1.1 million for federal and state purposes, offset by a tax benefit of \$0.4 million from the sale of certain state net operating loss carryforwards. In 2002, we recorded a net income tax benefit of approximately \$0.1 million, which reflected income tax expense of \$0.6 million for state purposes offset by a tax benefit of \$0.7 million from the sale of certain state net operating loss carryforwards.

INCOME (LOSS) FROM CONTINUING OPERATIONS: Income (loss) from continuing operations and per common share amounts for the years ended December 31, 2004, 2003 and 2002 were as follows:

(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)			
	2004	2003	2002
		As restated	As restated
Income (loss) from continuing Operations	\$ 52,756	\$ 24,943	\$ (91,492)
Per common share amounts:			
Basic	\$ 0.32	\$ 0.15	\$ (0.60)
Diluted	\$ 0.31	\$ 0.14	\$ (0.60)
Weighted average number of shares of common stock utilized to calculate per common share amounts:			
Basic	163,869	161,774	154,674
Diluted	172,855	170,796	154,674



2004 COMPARED TO 2003: Income from continuing operations increased in 2004 from 2003 due to an increase in total revenue of approximately \$106.0 million (attributable primarily to an increase in THALOMID(R) net sales) partly offset by higher operating expenses of approximately \$60.7 million and a decrease in interest and other income, net of approximately \$7.9 million (attributable to a \$1.9 million decrease in fair value of EntreMed warrants versus a prior year increase of \$16.6 million partly offset by an increase in interest income and foreign exchange gains and the inclusion in 2003 of equity losses of associated companies of \$4.4 million).

2003 COMPARED TO 2002: In 2003, we recorded income from continuing operations for the first time since our inception in 1986. Income from continuing operations increased in 2003 from 2002 due to an increase in total revenues of approximately \$135.8 million (attributable primarily to an increase in THALOMID(R) net sales and first-time ALKERAN(R) sales that resulted from executing the ALKERAN(R) supply and distribution agreement with GSK in March of 2003) and a \$9.7 million increase in interest and other income, net primarily due to a \$16.6 million increase in the fair value of EntreMed warrants. Partially offsetting these increases were higher operating expenses of approximately \$23.8 million and the inclusion in 2003 of equity losses of associated companies of \$4.4 million. Impacting the 2003 to 2002 operating expenses comparison were aggregate one-time costs of approximately \$78.4 million incurred in the 2002 period (\$55.7 million from the write-off of acquired in-process research and development related to the Anthrogenesis acquisition and \$22.7 million associated with the litigation settlement and related agreements with EntreMed, Inc. and CMCC).

GAIN ON SALE OF CHIRAL ASSETS: In January 1998, we completed the sale of our chiral intermediate business to Cambrex Corporation. Pursuant to the minimum royalty provisions of the agreement, we received approximately \$0.8 million and \$1.0 million in 2003 and 2002, respectively. For more information on the disposition of the chiral intermediates business, refer to Note 3 of our Notes to the Consolidated Financial Statements.

#### LIQUIDITY AND CAPITAL RESOURCES

Net cash provided by operating activities increased to approximately \$155.9 million in 2004 compared to \$18.7 million in 2003. The increase was primarily due to higher earnings, the receipt of \$80.0 million in connection with the December 2004 THALOMID(R) development and commercialization collaboration with Pharmion and a decrease in net working capital levels. Net cash provided by operating activities in 2003 increased approximately \$47.0 million from 2002. The increase in 2003 compared to 2002 was primarily due to higher earnings and the inclusion of \$22.7 million of spending in the 2002 period related to the litigation settlement and related agreements with EntreMed, Inc. and CMCC, partially offset by an increase in net working capital levels.

Net cash used in investing activities was \$92.6 million in 2004 compared to \$443.6 million in 2003. Included in the 2004 activities were cash outflows of \$109.9 million for the October 2004 acquisition of Penn T, \$7.0 million for an investment made in Royalty Pharma Strategic Partners, LP, which is classified in other assets on the consolidated balance sheet, and \$36.0 million for capital expenditures. Partially offsetting these outflows were cash inflows of approximately \$60.3 million from net marketable securities sales. Included in the 2003 activities were cash outflows of \$421.2 million for net marketable securities purchases, \$12.0 million for the purchase of a Pharmion Corporation senior convertible note and \$11.2 million for capital expenditures. In 2002, approximately \$63.3 million of net cash was provided by investing activities, which was due to cash inflows of approximately \$93.1 million from net marketable securities sales, offset by cash outflows of \$11.1 million for capital expenditures, \$10.3 million related to the December 2002 acquisition of Anthrogenesis and \$9.5 million for the value ascribed to the EntreMed convertible preferred shares and warrants received in connection with the December 31, 2002 litigation settlement and related agreements with EntreMed.

The Company previously followed the common practice of classifying its investments in auction rate notes as cash and cash equivalents on the consolidated balance sheet. It was determined that these instruments are not cash equivalents and therefore, the Company has made a reclassification to its

Consolidated Balance Sheet as of December 31, 2003 in order to conform to the current year's presentation. The reclassification resulted in a decrease in cash and cash equivalents and a corresponding increase in marketable securities available for sale as of December 31, 2003 of approximately \$207.1 million. The reclassification resulted in a net decrease of \$207.1 million in net cash provided by investing activities in 2003, which was comprised of the following components; an increase in the proceeds from the sale of marketable securities of \$229.2 million and an increase in the purchase of marketable securities of approximately \$436.3 million. The Company did not hold such securities in 2002.

Net cash provided by financing activities was approximately \$16.0 million, \$399.7 million and \$3.4 million in 2004, 2003 and 2002, respectively, and included cash inflows from the exercise of common stock options and warrants of approximately \$16.3 million, \$12.0 million and \$4.0 million in 2004, 2003 and 2002, respectively. Included in 2003 were cash inflows of \$387.9 million from net proceeds of the issuance of our convertible notes on June 3, 2003

Currency rate changes negatively impacted our cash and cash equivalents balances by \$4.4 million in 2004. At December 31, 2004, cash, cash equivalents and marketable securities were \$748.5 million, an increase of \$81.6 million from December 31, 2003 levels and reflects the inclusion of 1,939,600 shares of Pharmion Corporation common stock, of which 1,150,511 shares were obtained in connection with the March 2004, conversion of the Pharmion Convertible Note and 789,089 shares were obtained in connection with the September 2004, exercise of Pharmion warrants. At December 31, 2004, the Pharmion common stock investment classified in marketable securities had an estimated fair value of \$81.9 million.

We expect increased research and product development costs, clinical trial costs, expenses associated with the regulatory approval process and commercialization of products and capital investments. However, existing cash, cash equivalents and marketable securities available for sale, combined with expected net product sales and revenues from various research, collaboration and royalties agreements are expected to provide sufficient capital resources to fund our operations for the foreseeable future.

#### CONTRACTUAL OBLIGATIONS

The following table sets forth our contractual obligations as of December 31, 2004:

(IN MILLIONS \$)	PAYMENT DUE BY PERIOD				TOTAL
	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS	
Convertible Note Obligations	\$ --	\$ --	\$400.0	\$ --	\$400.0
Operating leases	3.6	6.7	5.6	6.3	22.2
ALKERAN(R) supply and distribution agreement	20.0	5.0	--	--	25.0
Employment agreements	2.6	0.7	--	--	3.3
Other contract commitments	5.8	7.5	4.4	--	17.7
	\$ 32.0	\$ 19.9	\$410.0	\$ 6.3	\$468.2

CONVERTIBLE NOTE OBLIGATIONS: In June 2003, we issued an aggregate principal amount of \$400 million of unsecured convertible notes to qualified institutional investors. The convertible notes have a five-year term and a coupon rate of 1.75% payable semi-annually commencing December 1, 2003. The convertible notes have a stock split adjusted conversion rate of \$24.225 per share, which represented a 50% premium to our closing stock price of \$16.15, after adjusting prices for the two-for-one stock split effected on October 22, 2004, on May 28, 2003. The debt issuance costs related to these convertible

notes, which totaled approximately \$12.2 million, are classified under "Other Assets" on the Consolidated Balance Sheet and are being amortized over five years, assuming no conversion. Under the terms of the purchase agreement, the noteholders can convert the notes at any time into 16,511,840 shares of common stock at the conversion price. In addition, the noteholders have the right to require us to redeem the notes in cash at a price equal to 100% of the principal amount to be redeemed, plus accrued interest, prior to maturity in the event of a change of control and certain other transactions defined as a "fundamental change" within the agreement. We have registered the notes and common stock issuable upon conversion with the Securities and Exchange Commission, and we are required to use reasonable best efforts to keep the related registration statement effective for the defined period. Pursuant to the indenture governing the notes, we may not merge or transfer substantially all assets, as defined, unless certain conditions are met.

**OPERATING (FACILITIES) LEASES:** We lease an aggregate of 92,100-square feet of laboratory and office space in Warren, New Jersey, under various leases with unaffiliated parties, which have lease terms ending between June 2005 and July 2010 with renewal options ranging from either one or two additional five-year terms. Annual rent for these facilities is approximately \$1.0 million. We also are required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. We also lease an 18,000-square foot laboratory and office facility in North Brunswick, New Jersey, under a lease with an unaffiliated party that has a term ending in March 2009 with two five-year renewal options. Annual rent for this facility is approximately \$0.5 million.

In November 2004, we purchased land and several buildings in Summit, New Jersey, which will enable us to consolidate four New Jersey locations into one corporate headquarters and provide the room to accommodate our anticipated growth. As a result, we are currently exploring available options to reduce or eliminate the financial impact of existing lease commitments on redundant facilities.

In connection with our acquisition of Anthrogenesis in December 2002, we assumed two separate leases in the same facility for office and laboratory space in Cedar Knolls, New Jersey and have subsequently entered into one additional lease for additional space in the same facility. The leases are for an aggregate 20,000-square feet with annual rent of approximately \$0.2 million. We also are required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. The leases have terms ending between September 2007 and April 2009 with renewal options ranging from either one or two additional five-year terms. In November of 2002, Anthrogenesis entered into a lease for an additional 11,000 square feet of laboratory space in Baton Rouge, Louisiana. The lease has a five-year term with a three-year renewal option. Annual rent for this facility is approximately \$0.1 million.

We lease a 78,202-square foot laboratory and office facility in San Diego, California from an unaffiliated party, which has a term ending in August 2012 with one five-year renewal option. Annual rent for this facility is approximately \$1.9 million and is subject to specified annual rental increases. Under the lease, we also are required to reimburse the lessor for real estate taxes, insurance, utilities, maintenance and other operating costs.

For a schedule of payments related to operating leases, refer to Note 18 of the Notes to the Consolidated Financial Statements.

**ALKERAN(R) PURCHASE COMMITMENTS.** In March 2003, we entered into a three-year supply and distribution agreement with GSK to distribute, promote and sell ALKERAN(R) (melphalan), a therapy approved by the FDA for the palliative treatment of multiple myeloma and carcinoma of the ovary. Under the terms of the agreement, we purchase ALKERAN tablets and ALKERAN for infusion from GSK and distribute the products in the United States under the Celgene label. The agreement requires that we purchase certain

minimum quantities each year for an initial three-year term under a take-or-pay arrangement aggregating \$56.6 million over such period and is automatically extended by successive one-year periods, unless at least one-year prior to the renewal date, either party advises the other party that it elects not to extend the agreement. At December 31, 2004, the remaining minimum purchase requirements under the agreement totaled \$25.0 million.

**EMPLOYMENT AGREEMENTS:** We have employment agreements with certain officers and employees. Employment contracts provide for base compensation and an annual target bonus based upon achievement of our performance measures and annual increases in base compensation reflecting annual reviews and related salary adjustment. The outstanding commitment for base compensation related to employment contracts as of December 31, 2004 was approximately \$2.6 million for 2005 and \$0.7 million for 2006 (excluding any change in control provisions).

**OTHER CONTRACT COMMITMENTS:** We signed an exclusive license agreement with CMCC, terminating any existing thalidomide analog agreements between CMCC and Entremed and directly granting to us an exclusive worldwide license by CMCC for the analog patents. Under the agreement, we are required to pay CMCC \$2.0 million between 2005 and 2006, the present value of which was expensed in 2002. Additional payments are possible under the agreement depending on the successful development and commercialization of thalidomide analogs.

On October 21, 2004, the Company, through an indirect wholly-owned subsidiary, acquired all of the outstanding shares of Penn T Limited, or Penn T, a worldwide supplier of THALOMID(R), from a consortium of private investors. Penn T was subsequently renamed Celgene UK Manufacturing II, Limited, or CUK II. In connection with the acquisition, we and CUK II entered into a technical services agreement with Penn Pharmaceutical Services Limited, or PPSL, and Penn Pharmaceutical Holding Limited pursuant to which PPSL provides the services and facilities necessary for the manufacture of THALOMID(R) and other thalidomide formulations. The total cost over the five-year minimum agreement period is approximately \$11.0 million.

In October 2003, we signed an agreement with Institute of Drug Technology Australia Limited, or IDT, for the manufacture of finished dosage form of THALOMID(R) capsules. The agreement requires minimum payments for THALOMID(R) capsules of \$4.7 million for the three-year term commencing with the FDA's approval of IDT as an alternate supplier. The agreement provides us with additional capacity and reduces our dependency on one manufacturer for the production of THALOMID(R). As of December 31, 2004, the FDA has not approved such alternate supplier.

#### 2005 FINANCIAL OUTLOOK

In our January 27, 2005 earnings release, we set forth our initial earnings estimate for the full year 2005. Although we believe that the January 27, 2005 estimate continues to reflect our current thinking, there can be no assurance that revenues or earnings will develop in the manner projected or if the analysis, on which the projection were based, were to be redone on the date hereof that there would be no change in the guidance.

**REVENUES:** Our initial 2005 financial guidance anticipates total revenue in the range of \$525 million, with THALOMID(R) revenues targeted in the range of \$400 million. Our 2005 revenue forecast for the RITALIN(R) family of drugs remains at approximately \$60 million, which includes a payment for the approval of FOCALIN(R) XR. Our initial financial guidance does not include REVLIMID(R) product sales, nor does it include expenses associated with the potential commercial launch of REVLIMID(R). As regulatory timelines become more certain we will update this guidance.

R&D EXPENSES: Research and development expenses are expected to increase to the \$190 million range in 2005. Important components of the increased spending include (1) expansion of both United States and European regulatory programs directed toward hematological and malignant blood disorders, (2) spending for the investigation of agents in solid tumor clinical trials, and (3) the potential advancement of compounds in our discovery programs, including PDE4/TNF-alpha inhibitors, kinase inhibitors, ligase inhibitors, benzopyrans and placental-derived stem cells into our pre-clinical and clinical development pipeline

SG&A EXPENSES: Selling, general and administrative expenses are expected to increase to the \$140 million range in 2005, which includes increased spending for the commercial support of THALOMID(R) and ALKERAN(R) and expand our commercial and manufacturing capabilities in the United Kingdom and Switzerland. This guidance excludes the potential costs of employee's stock options.

#### NEW ACCOUNTING PRINCIPLES

In December 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 123R, "Share-Based Payment", or SFAS 123R, that addresses the accounting for share-based payment transactions in which employee services are received in exchange for either equity instruments of the company, liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R addresses all forms of share-based payment awards, including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. SFAS No. 123R eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25, "Accounting for Stock Issued to Employees", that was provided in Statement 123 as originally issued. Instead, under SFAS No. 123R companies are required to record compensation expense for all share-based payment award transactions measured at fair value. This statement is effective for quarters ending after June 15, 2005. We are currently evaluating the impact of adopting this statement.

Emerging Issues Task Force, or EITF, Issue No. 03-01, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," or EITF 03-01, was issued in February 2004. EITF 03-01 stipulates disclosure requirements for investments with unrealized losses that have not been recognized as other-than-temporary impairments. The provisions of EITF 03-01 are effective for fiscal years ending after December 15, 2003. We have complied with the disclosure provisions of EITF 03-01. In September 2004, the FASB staff issued two proposed FASB Staff Positions, or FSP: Proposed FSP EITF Issue 03-1-a, which provides guidance for the application of paragraph 16 of EITF Issue 03-1 to debt securities that are impaired because of interest rate and/or sector spread increases, and Proposed FSP EITF Issue 03-1-b, which delays the effective date of Issue 03-1 for debt securities that are impaired because of interest rate and/or sector spread increases. We are currently monitoring these developments to assess the potential impact on our financial position and results of operations.

EITF Issue No. 03-6, "Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings Per Share." In April 2004, the EITF issued Statement No. 03-6, "Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings Per Share." EITF 03-6 addresses a number of questions regarding the computation of earnings per share by a company that has issued securities other than common stock that contractually entitle the holder to the right to participate in dividends when, and if, declared. The issue also provides further guidance in applying the two-class method of calculating earnings per share, clarifying the definition of a participating security and how to apply the two-class method. EITF 03-6 was effective for fiscal periods beginning after March 31, 2004 and was required to be retroactively applied. We evaluated the terms of our convertible notes and

debentures and determined that none of these instruments qualified as participating securities under the provisions of EITF 03-6. As a result, the adoption of EITF 03-6 had no impact on the Company.

EITF Issue No. 02-14, "Whether an Investor Should Apply the Equity Method of Accounting to Investments Other Than Common Stock," or EITF 02-14, is effective in the fourth quarter of 2004. EITF 02-14 states that an investor should only apply the equity method of accounting when it has investments in either common stock or in-substance common stock. EITF 02-14 also provides characteristics to be evaluated in determining whether an investment in other than common stock is in-substance substantially similar to an investments in that entity's common stock and thus, accounted for under the equity method. For investments that are not common stock or in-substance common stock, but were accounted for under the equity method, EITF 02-14 requires discontinued use of the equity method of accounting prospectively for reporting periods beginning after September 15, 2004. Previously recognized equity method earnings and losses should not be reserved.

Based on the above guidance, the Company concluded that its EntreMed voting preferred stock investments, which had previously been written-down to zero under the equity method of accounting, was not in-substance common stock as defined in EITF 02-14 and therefore, discontinued use of the equity method of accounting beginning on October 1, 2004. Prospectively, the Company will account for such investment under the cost method since the preferred stock is not publicly traded. This change does not impact the carrying value of the EntreMed preferred stock investment and accordingly, did not have an impact on the Company's consolidated financial statements.

#### CRITICAL ACCOUNTING POLICIES

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 of the Notes to the Consolidated Financial Statements included in this annual report, we believe the following accounting policies to be critical:

**REVENUE RECOGNITION ON COLLABORATION AGREEMENTS:** We have formed collaborative research and development agreements and alliances with several pharmaceutical companies. These agreements are in the form of research and development and license agreements. The agreements are for both early- and late-stage compounds and are focused on specific disease areas. For the early-stage compounds, the agreements are relatively short-term agreements that are renewable depending on the success of the compounds as they move through preclinical development. The agreements call for nonrefundable upfront payments, milestone payments on achieving significant milestone events, and in some cases ongoing research funding. The agreements also contemplate royalty payments on sales if and when the compound receives FDA marketing approval.

In accordance with Staff Accounting Bulletin No. 104, or SAB 104, "REVENUE RECOGNITION IN FINANCIAL STATEMENTS," upfront payments are recorded as deferred revenue and recognized over the estimated service period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis. Continuation of certain contracts is dependent upon our achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project. Revenue under research contracts is recorded as earned under the contracts, as services are provided.

SAB No. 104 updates the guidance in SAB No. 101 and requires companies to identify separate units of accounting based on the consensus reached on Emerging Issues Task Force, or EITF, Issue No. 00-21, "REVENUE ARRANGEMENTS WITH MULTIPLE DELIVERABLES", or EITF 00-21. EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. EITF 00-21 is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF's separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue-recognition policy must be determined for the entire arrangement. Prior to the adoption of EITF 00-21, revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, were recognized when and if the milestones were achieved.

**GROSS TO NET SALES ACCRUALS FOR SALES RETURNS, MEDICAID REBATES AND CHARGEBACKS** We record an allowance for sales returns based on the actual returns history for consumed lots and the trend experience for lots where product is still being returned. We record Medicaid rebate accruals based on historical payment data and estimates of Medicaid beneficiary utilization. We record chargeback accruals based on actual sales to customers who are covered under federally qualified programs.

DEFERRED TAX ASSET VALUATION ALLOWANCE: We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

ACCOUNTING FOR LONG-TERM INCENTIVE PLANS: The recorded liability for long-term incentive plans was \$3.9 million as of December 31, 2004. Plan payouts may be in the range of 0% to 200% of the participant's salary for the 2005 Plan and 0% to 150% of the participant's salary for the 2006 Plan and the maximum potential payouts are \$6.1 million and \$4.9 million for the 2005 and 2006 Plans, respectively. Upon a change in control, participants will be entitled to an immediate payment equal to their target award, or, if higher, an award based on actual performance through the date of the change in control.

ENTREMED WARRANTS: We hold warrants to purchase up to 7,000,000 shares of Entremed common stock. The warrants have an exercise price of \$1.50 per share and expire seven years from the date of grant. The warrants are accounted for as a derivative instrument under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." Under SFAS 133, the warrants are recorded on the balance sheet at fair value and are marked to market, with gains and losses recognized in earnings. The warrants were recorded on the balance sheet at \$19.8 million and \$21.7 million at December 31, 2004 and 2003, respectively. Fair value is estimated using a Black-Scholes options pricing model incorporating management assumptions about expected term and volatility.

BUSINESS COMBINATIONS: The Penn T and Anthrogenesis acquisitions completed in October 2004 and December 2002, respectively, have been accounted for under the provisions of SFAS No. 141, "Business Combinations," which requires the use of the purchase method. Under SFAS 141, the purchase price is allocated to the assets received and liabilities assumed based upon their respective fair values. The initial purchase price allocations may be adjusted within one year of the purchase date for changes in the estimated fair value of assets acquired and liabilities assumed. The resulting goodwill, which represents the excess of costs of an acquired entity over the fair value of identifiable assets acquired and liabilities assumed, and intangible assets are accounted for under SFAS No. 142, "Goodwill and Other Intangible Assets." Under SFAS 142, goodwill and intangible assets determined to have an indefinite useful life are not amortized, but instead are tested for impairment at least annually. Intangible assets with estimable useful lives are amortized to their estimated residual values over their respective estimated useful lives, and reviewed for impairment in accordance with SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets."

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings.

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At December 31, 2004, our market risk sensitive instruments consisted of marketable securities available for sale, warrants to purchase up to 7,000,000 shares of Entremed common stock and unsecured convertible notes issued by the Company.

MARKETABLE SECURITIES AVAILABLE FOR SALE: At December 31, 2004, our marketable securities available for sale consisted of U.S. government agency mortgage obligations, U.S. government agency bonds, corporate debt securities and 1,939,600 shares of Pharmion common stock. Marketable securities available for sale are carried at fair value, are held for an indefinite period of time and are intended to be used to meet our ongoing liquidity needs. Unrealized gains and losses on available for sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of all debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses, is included in interest and other income.

As of December 31, 2004, the principal amounts, fair values and related weighted average interest rates of the Company's investments in debt securities classified as marketable securities available-for-sale were as follows:

(IN THOUSANDS \$)	DURATION					TOTAL
	0 TO 1 YEAR	FIXED RATE SECURITIES 1 TO 3 YEARS	3 TO 5 YEARS	5 TO 7 YEARS	VARIABLE RATE SECURITIES	
Principal amount	\$287,443	\$108,996	\$ 30,264	\$ 83,425	\$ 20,513	\$530,641
Fair value	\$288,542	\$112,424	\$ 31,895	\$ 80,862	\$ 17,717	\$531,440
Average interest rate	2.98%	4.33%	4.92%	5.81%	5.88%	3.93%

PHARMION COMMON STOCK: In March 2004, we converted our \$12.0 million Pharmion Senior Convertible Note investment, which had accrued interest of approximately \$0.7 million, into 1,150,511 shares of Pharmion common stock. Additionally, in September 2004, we exercised a total of 789,089 warrants to purchase shares of Pharmion common stock, which we had received in connection with previous transactions with Pharmion Corporation, (i.e., the November 2001 license agreement and the April 2003 securities purchase agreement). As a result of these transactions, at December 31, 2004, we held a total of 1,939,600 shares of Pharmion Corporation common stock, which had an estimated fair value of approximately \$81.9 million (based on the closing price reported by the National Association of Securities Dealers Automated Quotations, or NASDAQ system, and, which exceeded the cost by approximately \$61.7 million. The amount by which the fair value exceeded the cost (i.e., the unrealized gain) was included in Accumulated Other Comprehensive Income in the Stockholders' Equity section of the Consolidated Balance Sheet. The fair value of the Pharmion common stock investment is subject to market price volatility and any increase or decrease in Pharmion's common stock quoted market price will have a similar percentage increase or decrease in the fair value of our investment.

ENTREMED WARRANTS: In connection with the December 31, 2002, litigation settlement and related agreements with Entremed Corporation and CMCC, we received warrants to purchase 7,000,000 shares of Entremed common stock. The warrants have an exercise price of \$1.50 per share and expire seven years from the date of grant. Based on Entremed's closing stock price on December 31, 2004, of \$3.24, the intrinsic value of the warrants is approximately \$12.2 million and the fair value using a Black-Scholes options pricing model is estimated to be approximately \$19.8 million. Since the warrants give us the right, but not an obligation, to purchase the shares of Entremed common stock, the warrants can never result in a cumulative negative charge to earnings.

CONVERTIBLE DEBT: In June 2003, we issued an aggregate principal amount of \$400.0 million of unsecured convertible notes. The convertible notes have a five-year term and a coupon rate of 1.75% payable semi-annually. The convertible notes can be converted at any time into 16,511,840 shares of common stock at a stock split adjusted conversion price of \$24.225 per share (for more information see Note 10 of the Notes to the Consolidated Financial Statements). At December 31, 2004, the fair value of the convertible notes exceeded the carrying value of \$400.0 million by approximately \$117.0 million, which we believe reflects the increase in the market price of the Company's common stock to \$26.52 per share as of December 31, 2004. Assuming other factors are held constant, an increase in interest rates generally results in a decrease in the fair value of fixed-rate convertible debt, but does not impact the carrying value, and an increase in the Company's stock price generally results in an increase in the fair value of convertible debt, but does not impact the carrying value.



ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Part IV, Item 15 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A CONTROLS AND PROCEDURES

- (a) As of the end of the period covered by this annual report, we carried out an evaluation, under the supervision and with the participation of the Company's management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)). Based upon the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

Management's report on the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), and the related report of our independent registered public accounting firm, are included in our 2004 Financial Report under the headings MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING and REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM, respectively, and are incorporated by reference.

- (b) Changes in Internal Control Over Financial Reporting. In connection with our quarterly review of accounting procedures and issues during the fourth quarter of 2004 the Company reviewed their accounting for warrants received during the EnterMed transaction of December 31, 2002. Based on this review the Company determined that the warrants, which had previously been considered as part of our equity investment under APB 18, should have been accounted for as derivatives under SFAS 133. (See Footnote 2). Accordingly, the Company has restated the 2003 and 2002 financial statements to reflect this accounting. Prior to the the fourth quarter of 2004, our technical review of the accounting for warrants, specifically the consideration of the application of SFAS 133 was viewed as a material weakness in internal controls. The weakness was remediated before year-end by expanding our knowledge of SFAS 133 and engaging outside experts to assist in reviewing technical matters. Our expanded knowledge in this area in conjunction with our quarterly review of accounting procedures and issues led to our identification of this matter. There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 and 15d-15 that occurred during our latest fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement (or an amendment to our Annual Report on Form 10-K) to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2004 in connection with our 2005 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

See Item 10.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

See Item 10.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

See Item 10.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

See Item 10.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) (1), (a) (2) See Index to Consolidated Financial Statements and Consolidated Financial Statement Schedule immediately following Signatures and Power of Attorney.

(b) Exhibits

The following exhibits are filed with this report or incorporated by reference.

EXHIBIT NO.	EXHIBIT DESCRIPTION
2.1	Purchase Option Agreement and Plan of Merger, dated April 26, 2002, among the Company, Celgene Acquisition Corp. and Anthrogenesis Corp. (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form S-4 dated November 13, 2002 (No. 333-101196)).
2.2	Amendment to the Purchase Option Agreement and Plan of Merger, dated September 6, 2002, among the Company, Celgene Acquisition Corp. and Anthrogenesis Corp. (incorporated by reference to Exhibit 2.2 to the Company's Registration Statement on Form S-4 dated November 13, 2002 (No. 333-101196)).
2.3	Asset Purchase Agreement by and between the Company and EntreMed, Inc., dated as of December 31, 2002 (incorporated by reference to Exhibit 99.6 to the Company's Schedule 13D filed on January 3, 2003).
2.4	Securities Purchase Agreement by and between EntreMed, Inc. and the Company, dated as of December 31, 2002 (incorporated by reference to Exhibit 99.2 to the Company's Schedule 13D filed on January 3, 2003).
2.5	Share Acquisition Agreement for the Purchase of the Entire Issued Share Capital of Penn T Limited among Craig Rennie and Others, Celgene UK Manufacturing Limited and the Company dated October 21, 2004 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K dated October 26, 2004).
3.1	Certificate of Incorporation of the Company, as amended (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1, dated July 24, 1987).
3.2	Bylaws of the Company (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, dated September 16, 1996).
4.1	Rights Agreement, dated as of September 16, 1996, between the Company and American Stock Transfer & Trust Company (incorporated by reference to the Company's Registration Statement on Form 8A, filed on September 16, 1996), as amended on February 18, 2000 (incorporated by reference to Exhibit 99 to the Company's Current Report on Form 8-K filed on February 22, 2000), as amended on August 13, 2003